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Ammonium Sulfamate
Pesticide Registration Standard

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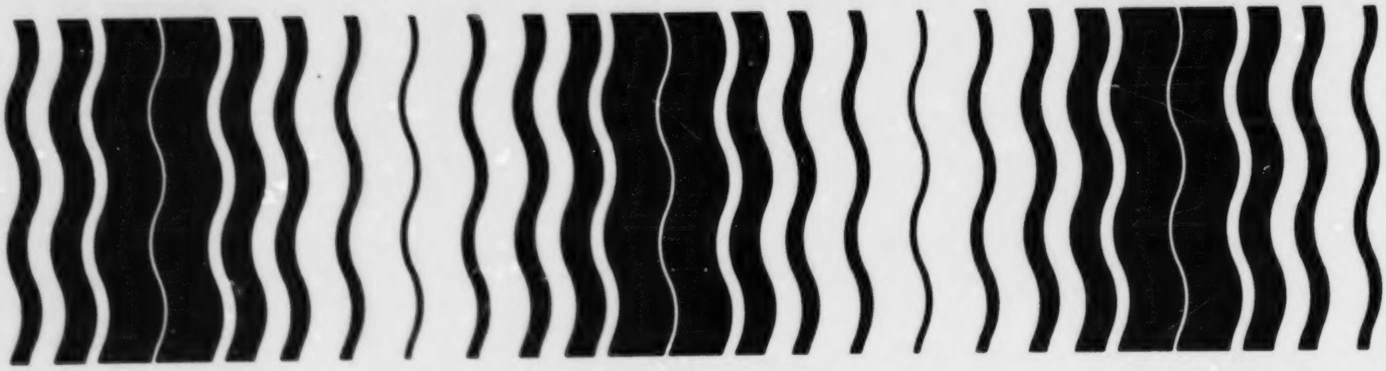
Ammonium Sulfamate

Pesticide Registration Standard



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This document contains information regarding reregistration of pesticide products containing Ammonium Sulfamate, including how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also, included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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AMMONIUM SULFAMATE

PESTICIDE REGISTRATION STANDARD

Lois Rossi	Project Manager (SPRD)
Anne Barton	Science Policy Staff (HED)
William Boodee	Residue Chemist (HED)
Wayne Faatz	Wildlife Biologist (HED)
Ralph Freund	Economist (BFSD)
Randy Norris	Editor (SPRD)
Pat Ott	Environmental Chemist (HED)
Donna Peacher	Typist (SPRD)
Bruce Sidwell	Plant Scientist (BFSD)
Ellen Sullivan	Toxicologist (HED)
Dorothy Vaughn	Typist (SPRD)
Vickie Walters	Product Manager (RD)

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Office of Pesticides and Toxic Substances

Environmental Protection Agency

401 M Street, SW

Washington, D.C. 20460

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CHAPTER I: HOW TO REGISTER UNDER A REGISTRATION STANDARD

1. Organization of the Standard
2. Purpose of the Standard
3. Requirement to Re-register Under the Standard
4. "Product Specific" Data and "Generic" Data
5. Data Compensation Requirements under FIFRA 3(c)(1)(D)
6. Obtaining Data to Fill " Data Gaps"; FIFRA 3(c)(2)(B)
7. Amendments to the Standard

1. Organization of the Standard

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or re-registering under a Standard. The second chapter sets forth the requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapters, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

2. Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

> "(A) its composition is such as to warrant the proposed claims for it;
>
> (B) its labeling and other material required to be submitted comply with the requirements of this Act;
>
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
>
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. But the established approach to making these findings has been found to be defective on two counts:

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a "product by product" basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the "product by product" approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 2, 1978), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to re-register all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements, [See FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the "product by product" approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use pesticide safely, responsibly, and in accordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in the second chapter.

3. Requirement to Reregister Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Congress also agreed that reregistration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for reregistration. His application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for reregistration set forth in the Guidance Package which accompanies this Standard.

4. "Product Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 43 FR 29696, July 10, 1978; 43 FR 37336, August 22, 1978; and 45 FR 72948, November 3, 1980, as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories. (See the third chapter.) The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

A. Data that are product specific, i.e. data that relates only to the the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

B. Generic data that pertains to the properties or effects of a particular ingredient, and thus is relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or reregistration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product specific" data on any product other than the applicant's is irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the Standard so indicates.) "Product specific" data on the efficacy of particular end-use products is also required where the exact formulation may affect efficacy and where failure of efficacy could cause public health problems.

All other data needed to evaluate pesticide products concerns the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert", ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient [e.g., the acute LD-50 of the active ingredient in its technical or purer grade; see proposed 40 CFR 163.81-1(a), 43 FR 37355].

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see, e.g., proposed 40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide. But if an end-use product's label specified it was for use only in ways that involved no food/feed exposure and no repeated human exposure, the subchronic oral dosing study would not be required to evaluate the product's safety; and if a manufacturing-use product's label states that the product is for use only in making end-use products not involving food/feed use or repeated human exposure, that subchronic oral study would not be relevant to the evaluation of the manufacturing-use product either.

If a registrant of a currently registered manufacturing-use or end-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that is required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he reregisters his product. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

5. Data Compensation Requirements under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, reregistration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered is all data which are described by all the following criteria:

A. The data were first submitted to EPA (or to its predecessor agencies, USDA or FDA), on or after January 1, 1970;

B. The data were submitted to EPA (or USDA or FDA) by some other applicant or registant in support of an application for an experimental use permit, an amendment adding a new use to a registration, or for registration, or to support or maintain in effect an existing registration;

C. They are the kind of data which are relevant to the Agency's decision to register or reregister the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);

D. The Agency has found the data to be valid and usable in reaching regulatory conclusions; and

E. They are not data for which the applicant has been exempted by FIFRA Section 3(c)(2)(D) from the duty to offer to pay compensation. (This exemption applies to the "generic" data concerning the safety of an active ingredient of the applicant's product, not to "product specific" data. The exemption is available only to applicants whose product is labeled for end-uses for which the active ingredient in question is present in the applicant's product because of his use of another registered product containing that active ingredient which he purchases from another producer.)

An applicant for reregistration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be required to offer to pay for "product specific" data submitted by another firm. In many, if not in most cases, data which is specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product, that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(C)(1)(D) for that data.

Each applicant for registration or reregistration of a manufacturing-use product, and each applicant for registration or reregistration of an end-use product, who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for reregistration (or new registration) under this Standard is found in the Guidance Package for this Standard.

6. Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registrability decisions) and have not been located in the published literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps".

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a section 3(c)(2)(B) order, his product's registration may be suspended until the data is submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in the third chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The Standard also points out that to be registrable under the Standard, a product must be supported by certain required "product specific" data. In some cases, the Agency may possess sufficient "product specific" data on one currently registered product, but may lack such data on another. Only those Standards which apply to a very small number of currently registered products will attempt to state definitively the " product specific" data gaps on a "product by product" basis. (Although the Standard will in some cases note which data that EPA does possess would suffice to satisfy certain "product specific" data requirements for a category of products with closely similar composition characteristics.)

As part of the process of reregistering currently registered products, EPA will issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps -- whether the data in question are "product specific" or "generic" -- in accordance with a schedule.

Persons who wish to obtain registrations for new products under this Standard will be required to submit (or cite) sufficient "product specific" data before their applications are approved. Upon registration, they will be required under Section 3(c)(2)(B) to take appropriate steps to submit data needed to fill "generic" data gaps. (We expect they will respond to this requirement by entering into cost-sharing agreements with other registrants who previously have been told they must furnish the data.) The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

7. Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from the Agency. When all the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and re-issued.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities. Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in the Guidance Package.

II

Regulatory Position

1. Introduction

This chapter describes in detail the Agency's regulatory position on products which contain ammonium sulfamate as the sole active ingredient. The regulatory position adopted by the Agency incorporates a number of considerations. Foremost among these considerations is an analysis of the registrability of products containing ammonium sulfamate based on the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations. The Agency's determination is presented below, and the rationale for this decision follows the position.

In addition to the basic regulatory decision and rationale, this chapter includes the following: criteria for the registration of ammonium sulfamate products under the Standard; acceptable ranges and limits for product composition, acute toxicity, and use pattern/application method; required labeling; tolerance reassessment.

The scientific basis for a decision presented in this chapter can be found by reading the various disciplinary chapters (Chapters IV-VIII) which provide summaries of available scientific data on ammonium sulfamate. The data requirements and data gaps are presented in Chapter III, Tables 1-3. Also, the reason for establishing a data requirement can be found in the footnotes of the tables in Chapter III and also in the topical discussion portion of Chapters IV-VIII. References to Agency guidelines for testing are provided when appropriate. In instances where the data requirements differ from the guideline requirements, the rationale is presented in the footnotes of the tables.

2. Description of Chemical

Ammonium sulfamate is an inorganic salt used as a herbicide on a variety of sites. It is a non-volatile, crystalline solid. Ammonium sulfamate also has the following non-pesticidal uses: flameproofing of textiles and paper products, for electroplating solutions, for generation of nitrous oxide gas. Only the herbicidal use of this chemical will be addressed in this standard.

Ammonium sulfamate is the accepted name for the chemical. The Weed Science Society of America (WSSA) has adopted the common name of "AMS". Trade names for this chemical include: "Ammate" and "Ikurin". The Chemical Abstracts Registry (CAS) number for ammonium sulfamate is 7773-06-0, and the EPA Shaughnessy number is 005501.

3. Regulatory Position for Products Containing Ammonium Sulfamate

Ammonium sulfamate as described in this Standard may be registered for sale, distribution, reformulation, and use in the United States. Considering information available to the Agency as of March 10, 1981, the Agency finds that none of the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations were met or exceeded for ammonium sulfamate.

The information available to the Agency at the time of the development of this Standard was very limited. The Agency does not have reason to believe that the use of this herbicide will cause unreasonable adverse effects when used in compliance with proper label directions and precautions. Ammonium sulfamate products currently registered may be reregistered subject to the conditions imposed for data requirements. New products may be registered under this Standard, and are subject to the same requirements.

4. Regulatory Rationale

Ammonium sulfamate was developed and introduced as an herbicide in the early 1940's for the control of woody plants. The chemical has had appreciable use as a herbicide since then, with annual production figures ranging from 3 to 10 million pounds.

Ammonium sulfamate products are registered for both domestic and nondomestic, terrestrial outdoor use. Also, since the chemical is used to control poison ivy in apple and pear orchards, it is considered to have a food use.

Acute toxicity data are available only for a soluble concentrate formulation of ammonium sulfamate. These data indicate a low toxicity potential. No adequate chronic studies are available. Insufficient data on a 19-month feeding study in rats and summary data for a rat reproduction study were submitted. No consistent toxic effects were observed on growth, reproductive performance, viability, or lactation, and no abnormal histopathological findings were reported by the authors.

Some data are available on the physical/chemical properties of ammonium sulfamate, but major gaps exist in the product chemistry data base. There are no acceptable studies for the ecological effects or environmental fate of ammonium sulfamate and, also, there is not adequate data on residues on apples, pears and their by-products. Therefore, the hazards and potential risks to humans and the environment as a result of exposure to ammonium sulfamate cannot be adequately assessed at this time.

The human accident data reported on this chemical included four incidents involving ammonium sulfamate alone and one incident involving ammonium sulfamate in combination with other chemicals. All of the persons involved in these incidents received emergency and precautionary medical attention. Three of the reported incidents consisted of accidental splashing of ammonium sulfamate in the eye and face. After the affected areas were washed throughly with water, no symptoms or injury persisted. One incident involved an agricultural worker who developed a respiratory illness after spraying ammonium sulfamate. However, the attending physician stated that the case was not one of pesticide poisoning. The case involving the ingestion of ammonium sulfamate in combination with other chemicals was an attempted suicide, but the subject remained asymptomatic.

Although some accidents have been reported for this chemical, the reported incidents were not of a serious nature and were treated effectively. The lack of substantive accident data is significant since this chemical has been used for approximately forty years.

In addition, the parent compound of ammonium sulfamate, sulfamic acid, was assigned the generally recognized as safe status (GRAS) as an indirect human food ingredient by the Food and Drug Administration (FR Notice Vol.44, No.31 - February 13, 1979, p.9402). The review conducted by FDA considered the health aspects of sulfamic acid as an ingredient of food packaging materials. An extensive search of the literature was conducted. No chronic studies relating to possible carcinogenicity, mutagenicity, or teratogenicity of sulfamic acid were available. The decision to classify sulfamic acid in the generally recognized as safe status (GRAS) as an indirect human food ingredient was done on the basis that there was no evidence in the available information on sulfamic acid that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when it is used in food-packaging materials as currently practiced or as it might be expected to be used for such purpose in the future.

5. Criteria for Registration Under the Standard

To be subject to this Standard, ammonium sulfamate products must meet the following conditions:

1. contain ammonium sulfamate as the sole active ingredient;
2. be within acceptable standards of product composition;
3. be within acceptable acute toxicity limits;
4. be labeled for acceptable end-uses; and
5. bear required labeling.

Manufacturing-use ammonium sulfamate products must bear label directions for formulations into acceptable end-uses.

The applicant for registration or reregistration of ammonium sulfamate products subject to the Standard must comply with all terms and conditions described in this Standard, including commitment to fill data gaps on a time schedule specified by the Agency and, when applicable, offer to pay compensation to the extent required by 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA], as amended, 7 U.S.C. 136 (c)(1)(D) and 136 (c)(2)(D).

The only registrant that has submitted data in support of ammonium sulfamate registrations, and has not waived rights to compensation for data, is E.I. DuPont de Nemours and Company.

Acceptable Ranges and Limits

A. Manufacturing-use Ammonium Sulfamate

1. Product Composition Standards

To be covered under this Standard, manufacturing-use ammonium sulfamate products must contain ammonium sulfamate as the sole active ingredient. Manufacturing-use ammonium sulfamate products with any percentage of active ingredient with appropriate certification of limits are acceptable under this Standard.

2. Acute Toxicity Limits

The Agency will consider registration of manufacturing-use ammonium sulfamate products in the following toxicity categories:

	I	II	III	IV
Acute Oral Toxicity	yes	yes	yes	yes
Acute Dermal Toxicity	yes	yes	yes	yes
Acute Inhalation Toxicity	yes	yes	yes	yes
Primary Eye Irritation	yes	yes	yes	yes
Primary Dermal Irritation	yes	yes	yes	yes

3. Use Patterns

To be covered under this Standard, manufacturing-use ammonium sulfamate products must be labeled for formulation into end-use pesticides which are intended for outdoor, domestic and/or nondomestic, terrestrial, and orchard applications.

B. End Use Ammonium Sulfamate - Crystalline, Soluble Concentrate, Ready-to-Use, Pressurized Liquid

1. Product Composition Standards

End use ammonium sulfamate products with any percentage of active ingredient are acceptable under this Standard with appropriate certification of limits.

Inert ingredients in food-use formulations must be cleared for such use under 40 CFR 180.1001. Currently, there are two inert ingredients used in ammonium sulfamate end use products that are not cleared. These two ingredients are listed in the Confidential Appendix to this Standard. Registrants of end use products with inert ingredients that have not been cleared in 40 CFR 180.1001 must either remove the ingredient from the product or obtain clearance.

2. Acute Toxicity Limits

The Agency will consider registration of any end use ammonium sulfamate products for domestic use with the following categories:

	I	II	III	IV
Acute Oral Toxicity	no	yes	yes	yes
Acute Dermal Toxicity	no	yes	yes	yes
Acute Inhalation Toxicity	no	yes	yes	yes
Primary Eye Irritation	no	yes	yes	yes
Primary Dermal Irritation	no	yes	yes	yes

To be registered for nondomestic use under this Standard, any end use ammonium sulfamate products must have established acute toxicity category II-IV ratings according to the following table:

	I	II	III	IV
Acute Oral Toxicity	no	yes	yes	yes
Acute Dermal Toxicity	no	yes	yes	yes
Acute Inhalation Toxicity	no	yes	yes	yes
Primary Eye Irritation	no	yes	yes	yes
Primary Dermal Irritation	no	yes	yes	yes

End use products that have estabished acute toxicity category II rating and are registered for domestic use must meet child resistant packaging requirements.

3. Use Patterns and Application Methods

To be registered under this Standard, end use products of ammonium sulfamate must be labeled as herbicides for one or more of the following uses:

food uses	non-food uses
Apples	Non-agricultural sites
Pears	Rangelands and pastures

The Agency finds that it must limit application rates not to exceed current levels because of a lack of adequate data needed to complete a hazard assessment. This is an interim measure which may need to be reassessed following the receipt of required data.

6. Required Labeling

All manufacturing-use and end-use ammonium sulfamate products must bear appropriate labeling as specified in 40 CFR 162.10. The guidance package for this Standard contains specific information regarding label requirements.

A. Manufacturing-use Products

1. Use Pattern Statements

All manufacturing-use ammonium sulfamate products must list on the label the intended end-uses of formulated products produced from the manufacturing-use product. In accordance with data to be submitted or cited, all ammonium sulfamate labels must bear the following statement:

> "For Formulation into End-Use Herbicide Products
> Intended Only for Domestic, (Non Domestic), Food (Non Food),
> Terrestrial, Outdoor Use."

2. Precautionary Statements

There are no unique precautionary statements which must appear on the ammonium sulfamate label. The guidance package provides an updated list of all precautionary statements which must appear for this type of product. The Agency may, after review of data to be submitted under this Standard, impose additional label requirements.

B. End Use Ammonium Sulfamate Products

There are no unique precautionary statements which must appear on the ammonium sulfamate label. The guidance package provides an updated list of all precautionary statements which must appear for this type of product.

The Agency may, after review of data to be submitted under this Standard,impose additional label requirements.

7. Tolerance Reassessment

A tolerance of 5 ppm in or on apples and pears has been established for residues of ammonium sulfamate (40 CFR 180.88). Based on these established tolerances for residues of ammonium sulfamate and on the assumption that each commodity contains residues which meet the established tolerance level, the theoretical human exposure to residues of ammonium sulfamate is calculated to be 0.2089 mg/day/1.5kg diet.

The established tolerances of 5 ppm for apples and pears are not supported by the available data. Residue data for apples and pears and validation of the residue methodology are required. No data are available concerning residues in apple pomace. Residue data for apple pomace are currently being reserved pending the results and evaluation of residue data on apples. The tolerances will be reassessed when residue data are submitted.

Since ammonium sulfamate is registered for use in rangelands and pastures, consideration must be given to potential residues in meat and milk and the establishment of tolerances for these commodities. Tolerances have not been established for ammonium sulfamate residues in meat and milk nor has an exemption for these tolerances been granted. No data are available on residues in meat and milk. Residue data are currently being reserved pending the results and evaluation of residue data on apples at a detectable level to determine if residues are present in dairy animal and cattle feedstuff and the receipt and evaluation of environmental fate data. Milk and meat residue data may be required if the fate data indicate that use of ammonium sulfamate in fruit orchards, pastures, and rangelands could result in exposure to grazing animals and residues in meat and milk.

III

Data Requirements and Data Gaps

Manufacturing-Use Ammonium Sulfamate

Table 1, entitled Ammonium Sulfamate Generic Data Requirements, includes those data that pertain to the properties or effects of ammonium sulfamate as an active ingredient. Thus, these data are relevant to an evaluation of the risks and benefits of all products containing ammonium sulfamate. Providing data to fill indicated gaps is the primary responsibility of the manufacturing-use product registrant(s). Registrants of end-use products which are not exempted by FIFRA Section 3(c)(2)(D) are also responsible for the submission of these data. Applicants for the registration or reregistration of manufacturing-use ammonium sulfamate products must acknowledge reliance on existing data which fill indicated data requirements under FIFRA 3(c)(1)(D). These data are listed under the column entitled Bibliographic Citation in this table.

Table 2, entitled Ammonium Sulfamate Product-Specific Data Requirements for Manufacturing-Use Products , includes those data that relate only to the properties or effects of a product with a specific composition. Thus, these data are required of each product to characterize the product's particular composition and physical/chemical properties, and acute toxicity. Providing data to fulfill these data requirements for a particular product is the responsibility of each applicant for the registration or reregistration of a manufacturing-use ammonium sulfamate product. If the Agency has in its possession product-specific data which fulfill a data requirement for a particular product, this is indicated in the guidance package accompanying this Standard.

Applicants for the registration of new manufacturing-use ammonium sulfamate products must submit all required product specific data or establish that the proposed product is substantially similar to another product for which the Agency has received acceptable product specific data.

If the Agency has determined that one or more existing manufacturing-use ammonium sulfamate products are substantially similar, then this, too, is indicated. Product specific data need not be acknowledged under FIFRA 3(c)(1)(D) unless the Agency or a registrant has established that a product is substantially similar to another product for which the Agency has received acceptable product specific data. If this should occur, the registrant(s) of the former product(s) is required to acknowledge reliance on these data.

End Use Products of Ammonium Sulfamate

Registrants of end-use ammonium sulfamate products not exempted by FIFRA Section 3(c)(2)(D) are responsible for the submission of "generic" data described in Tables 1 and 2 of this Chapter, in addition to the product specific data listed in Table 3.

Registrants of all end-use ammonium sulfamate products are advised that if data are not generated to fill generic data requirements for the manufacturing-use product(s), these registrations will be suspended. If continued availability of the manufacturing-use product is desired, this data must be supplied.

Table 3, entitled Ammonium Sulfamate Product-Specific Data Requirements for End-Use Products, includes those data that relate only to the properties or effects of an end-use product with a specific composition.

Table 1

Ammonium Sulfamate Product-Chemistry (See Chapter IV)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.61-8(1)	Color	Yes	Technical Grade	All	Cain, 1972 MRID# 05008521	No
163.61-8(2)	Odor	Yes	Technical Grade	No	—	Yes/October, 1981
163.61-8(3)	Melting Point	Yes	Technical Grade	All	Pan, 1971, MRID# 05016316	No
163.61-8(4)	Solubility	Yes	Technical Grade	No	—	Yes/October, 1981
163.61-8(5)	Stability	Yes	Technical Grade	No	—	Yes/October, 1981
163.61-8(6)	Ortanol/water partition coefficent	Yes	Technical Grade	No	—	Yes/October, 1981
163.61-8(7)	Physical State	Yes	Technical Grade	All	Cain, 1972, MRID# 05008521	No

These data requirements are current as of April, 1981. Refer to guidance package for update requirements.

Table 1 (Cont'd)

Ammonium Sulfamate Peoduct Chemistry (See Chapter IV)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.61-8(8)	Density or Specific Gravity	Yes	Technical Grade	No	—	Yes/October, 1981
163.61-8(9)	Boiling Point	No				
163.61-8(10)	Vapor Pressure	Yes	Technical Grade	No	—	Yes/October, 1981
163.61-8(11)	pH	Yes	Technical Grade	All	Pan, 1971, MRID# 05016316	No
	Dissociation Constant[1]	Yes	Technical Grade	No	—	Yes/October, 1981

1/ The dissociation constant of a chemical can be used in assessing the aquatic, terrestrial, and metabolic fate of the chemical. For water soluble compounds such as ammonium sulfamate, water will usually be the reaction medium of concern. Since dissociation data will tell the Agency the active species in water (the intact molecule or only the sulfamate anion), this piece of information is required to determine the behavior of ammonium sulfamate in the environment.

These data requirements are current as of April, 1981. Refer to guidance package for updated requirements.

Table 1 (Cont'd)

Ammonium Sulfamate Environmental Fate (See Chapter V)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.62-7(b)	Hydrolysis	Yes	See Footnote 3	No	—	Yes/October, 1981
163.62-7(c)	Photodegradation	Yes	See Footnote 3	No	—	Yes/October, 1981
163.62-8(b)	Aerobic soil metabolism	No 2/				
163.62-8(c)	Anaerobic soil metabolism	No				
163.62-8(d)	Anaerobic aquatic metabolism	No 2/				
163.62-8(e)	Aerobic aquatic metabolism	No 2/				
163.62-8(f)	Microbial metabolism					
	(2) effects of microbes on pesticides	No 1/				
	(3) effects of pesticides on microbes	No 1/				

1/ The requirement for the submission of these data is currently being reserved pending the review and modification of the testing protocols. Consequently, the absence of acceptable data does not constitute a data gap.
2/ The requirement for the submission of data is currently being reserved pending the receipt and evaluation of hydrolysis and photodegradation data. The results of the hydrolysis and photolysis data will determine if any additional testing is required.
3/ Technical or radio-labeled analytical grade.

These data requirements are current as of April, 1981. Refer to guidance package for updated requirements.

Table 1 (Cont'd)

Ammonium Sulfamate Environmental Fate (See Chapter V)
Generic Data Requirements

Guideline Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.62-8(g)	Activated sludge metabolism	No[1/]				
163.62-9(b)	Leaching	No[2/]				
163.62-9(c)	Volatility	No				
163.62-9(d)	Adsorption/ desorption	No[2/]				
163.62-9(e)	Water dispersal	No[2/]				
163.62-10(b)	Terrestrial field dissipation					
	(1) Field & vegetable crop	No				
	(2) Tree Fruit & nut crop uses	No[2/]				
	(3) Pasture land uses	No[2/]				
	(4) Domestic outdoor parks, ornamentals and turf uses	No[2/]				

1/ The requirement for the submission of data is currently being reserved pending the review and modification of the testing protocols. Consequently, the absence of acceptable data does not constitute a data gap.

2/ The requirement for the submission of data is currently being reserved pending the receipt and evaluation of hydrolysis and photodegradation data. The results of the hydrolysis and photolysis data will determine if any additional testing is required.

These data requirements are current as of April, 1981. Refer to guidance package for updated requirements.

Table 1 (Cont'd)

Ammonium Sulfamate Environmental Fate (See Chapter V)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
	(5) Rights of way, shelterbelts and related uses	No 2/				
163.62-10(c)	Aquatic field dissipation					
	(1) Aquatic food crop uses	No				
	(2) Aquatic noncrop uses	No 2/				
	(3) Specialized aquatic uses	No				
163.62-10(d)	Terrestrial/ aquatic (forest) field dissipation	No 2/				
163.62-10(e)	Aquatic impact uses (1) Direct discharge (2) Indirect discharge (3) Wastewater treatment	No				

2/ The requirement for the submission of data is currently being reserved pending the receipt and evaluation of hydrolysis and photodegradation data. The results of the hydrolysis and photolysis data will determine if any additional testing is required.

These data requirements are current as of April, 1981. Refer to guidance package for updated requirements.

Table 1 (Cont'd)

Ammonium Sulfamate Environmental Fate (See Chapter V)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.62-10(f)	Combination and tank mix field dissipation	No				
163.62-10(g)	Long term field dissipation study	No				
163.62-11(b)	Accumulation in rotational crops	No				
163.62-11(c)	Accumulation in irrigated crops	No				
163.62-11(d)	Fish accumulation	No				
163.62-11(e)	Special studies accumulation in aquatic noncrop uses	No				
163.62-13	Disposal and storage	No				

These data requirements are current as of April, 1981. Refer to guidance package for updated requirements.

Table 1 (Cont'd)

Ammonium Sulfamate Toxicology (See Chapter VI)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.81-1	Acute Oral Toxicity	Yes	Technical Grade	No	—	Yes/October, 1981
163.81-2	Acute Dermal Toxicity	Yes	Technical Grade	No	—	Yes/October, 1981
163.81-7	Acute Neurotoxicity	No				
163.82-1	Subchronic Oral Toxicity	Yes	Technical Grade	No	—	Yes/April, 1982
163.82-2	Subchronic 21-day Dermal Toxicity	Yes	Technical Grade	No	—	Yes/April, 1982
163.82-3	Subchronic 90-day Dermal Toxicity	No				
163.83-4	Subchronic Inhalation Toxicity	No				

These data requirements are current as of April, 1981. Refer to guidance package for updated requirements.

Table 1 (Cont'd)

Ammonium Sulfamate Toxicology (See Chapter VI)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.83-1	Chronic Feeding	No[1/]				
163.83-2	Oncogenicity	No[1/]				
163.83-3	Teratogenicity	Yes[2/]	Technical Grade	No	—	Yes/April, 1983
163.83-4	Reproduction	No[3/]	—	Partial	Sherman et al. 1964, MRID# 00004224	No
163.84-2 through 4	Mutagenicity	Yes[2/]	Technical Grade	No	—	Yes/April, 1982
163.85-1	Metabolism	No[1/]				

1/ The requirement for the submission of data is currently being reserved pending the receipt of requested residue data and environmental fate data.

2/ These data are required because ammonium sulfamate is registered for domestic use and significant exposure could result.

3/ A rat reproduction study (Sherman et al. 1964) containing summary data was submitted. Individual test animal data are required for this study to be considered adequate. However, the requirement for any further submission of data is currently being reserved pending the receipt of requested residue data and environmental fate data.

These data requirements are current as of April, 1981. Refer to guidance package for updated requirements.

Table 1 (Cont'd)

Ammonium Sulfamate Ecological Effects (See Chapter VIII)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.72-1	Fish Acute LC_{50}	Yes	Technical Grade	No	—	Yes/January, 1982
163.72-2	Acute Toxicity to Aquatic Invertebrates	Yes	Technical Grade	No	—	Yes/January, 1982
163.72-3	Acute Toxicity to Estuarine and Marine Organisms	No[1]				
163.72-4	Embryolarvae and Life-cycle Studies of Fish and Aquatic Invertebrates	No[1]				
163.72-5	Aquatic Organism Toxicity and Residue Studies	No[1]				
163.72-6	Simulated or Actual Field Testing for Aquatic Organisms	No[1]				

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[1] The requirement for submission of these data is currently reserved pending the results of the following tests: Fish Acute LC_{50}, Acute Toxicity to Aquatic Invertebrates.

These data requirements are current as of April, 1981. Refer to guidance package for updated requirements.

Table 1 (Cont'd)

Ammonium Sulfamate Ecological Effects (See Chapter VIII)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.71-1	Avian Single-Dose Oral LD_{50}	Yes	Technical Grade	No	—	Yes/January, 1982
163.71-2	Avian Dietary LC_{50}	Yes	Technical Grade	No	—	Yes/January, 1982
163.71-3	Mammalian Acute Toxicity	No				
163.71-4	Avian Reproduction	No				
163.71-5	Simulated and Actual Field Testing for Mammals and Birds	No				

These data requirements are current as of April, 1981. Refer to guidance package for updated requirements.

Table 1 (Cont'd)

Ammonium Sulfamate Residue Chemistry (See Chapter VII)
Generic Data Requirements

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
—	Metabolism in in Plants	Yes[1/]	Technical Grade	No	—	Yes/April, 1982
—	Metabolism in Animals	Yes[2/]	Technical Grade	No	—	Yes/April, 1982
—	Analytical Methods	Yes[3/]	Technical Grade	No	—	Yes/April, 1982
—	Residue Data: Crops- Apples; Pears	Yes[4/]	Technical Grade	No	—	Yes/April, 1982
—	Residue Data: Processed Crops- Apple pomace	No[5/]	Technical Grade			
—	Residue Data: Milk and Meat	No[6/]	Technical Grade			
—	Storage Stability	Yes	Technical Grade	No	—	Yes/April, 1982

1/ Plant metabolism data or an acceptable justification as to why plant metabolism data are not necessary, including a discussion of possible metabolites, must be submitted.

2/ Animal metabolism data or an acceptable justification as to why such data are not necessary, including a discussion of possible metabolites must be submitted.

3/ Analytical method for detecting residues of ammonium sulfamate is required.

4/ Data on the nature and amount of residues on apples and pears are required to support established tolerance levels. The results of these data will be used to assess possible dietary exposure to ammonium sulfamate; if residues can be expected in apple pomace, milk and meat; and determine if chronic toxicology testing will be required.

5/ Data are currently being reserved pending the results and evaluation of residue data on apples.

6/ Data are currently being reserved pending the results and evaluation of residue data on apples to determine if ammonium sulfamate residues are present on animal feedstuff; and environmental fate data to determine if ammonium sulfamate residues persist in the environment (pastures, rangelands) and result in exposure to grazing animals.

These data requirements are current as of April, 1981. Refer to guidance package for updated requirements.

Table 2

Product Chemistry (See Chapter IV)
Ammonium Sulfamate Product-Specific Data Requirements for Manufacturing-Use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.61-3	Product Identity and Disclosure of Ingredients	Yes	MUP	No	—	Yes/October, 1981
163.61-4	Description of Manufacturing Process	Yes	MUP	No	—	Yes/October, 1981
163.61-5	Discussion of Formation of Unint. Ingredients	Yes	MUP	No	—	Yes/October, 1981
163.61-6	Declaration and Certification of Ingredient Limits	Yes	MUP	No	—	Yes/October, 1981
163.61-7	Product Analytical Methods and Data	Yes	MUP	No	—	Yes/October, 1981
163.61-8(7)	Physical State	Yes	MUP	No	—	Yes/October, 1981
163.61-8(8)	Density or Specific Gravity	Yes	MUP	No	—	Yes/October, 1981
163.61-8(9)	Boiling Point	No				
163.61-8(11)	pH	Yes	MUP	No	—	Yes/October, 1981
163.61-8(12)	Storage Stability	Yes	MUP	No	—	Yes/October, 1981

These data requirements are current as of April, 1981. Refer to guidance package for updated requirements.

Table 2 (Cont'd)

Product Chemistry (See Chapter IV)
Ammonium Sulfamate Product-Specific Data Requirements for Manufacturing-Use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.61-8(13)	Flammability	Yes[1]	MUP	No	—	Yes/October, 1981
163.61-8(14)	Oxidizing or Reducing Action	Yes	MUP	No	—	Yes/October, 1981
163.61-8(15)	Explosiveness	Yes[2]	MUP	No	—	Yes/October, 1981
163.61-8(16)	Miscibility	Yes[3]	MUP	No	—	Yes/October, 1981
163.61-8(17)	Viscosity	Yes	MUP	No	—	Yes/October, 1981
163.61-8(18)	Corrosion Characteristics	Yes	MUP	No	—	Yes/October, 1981

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[1] Required for products containing a volatile, flammable ingredient.
[2] Required for products containing a potentially explosive ingredient.
[3] Required for products which may be diluted with petroleum solvents.

These data requirements are current as of April, 1981. Refer to guidance package for updated requirements.

Table 2 (Cont'd)

Ammonium Sulfamate Toxicology (See Chapter VI)
Product-Specific Data Requirements for Manufacturing-Use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.81-1	Acute Oral Toxicity	Yes*	MUP	No	—	Yes/October, 1981
163.81-2	Acute Dermal Toxicity	Yes*	MUP	No	—	Yes/October, 1981
163.81-3	Acute Inhalation Toxicity	Yes	MUP	No	—	Yes/October, 1981
163.81-4	Primary Eye Irritation	Yes	MUP	No	—	Yes/October, 1981
163.81-5	Primary Dermal Irritation	Yes	MUP	No	—	Yes/October, 1981
163.81-6	Dermal Sensitization	Yes	MUP	No	—	Yes/October, 1981

* Technical ammonium sulfamate and the manufacturing-use product have been determined to be the same. These requirements may be filled by data required in Table 1 entitled: "Ammonium Sulfamate Toxicology Generic Data Requirements for Manufacturing-Use Products."

These data requirements are current as of April, 1981. Refer to guidance package for updated requirements.

Table 3

Product Chemistry (See Chapter IV)
Ammonium Sulfamate Product-Specific Data Requirements for End-Use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.61-3	Product Identity and Disclosure of Ingredients	Yes	Each product	No	—	Yes/October, 1981
163.61-4	Description of Manufacturing Process	Yes	Each product	No	—	Yes/October, 1981
163.61-5	Discussion of Formation of Unint. Ingredients	Yes	Each product	No	—	Yes/October, 1981
163.61-6	Declaration and Certification of Ingredient Limits	Yes	Each product	No	—	Yes/October, 1981
163.61-7	Product Analytical	Yes	Each product	No	—	Yes/October, 1981
163.61-8(1)	Color	Yes	Each product	No	—	Yes/October, 1981
163.61-8(2)	Odor	Yes	Each product	No	—	Yes/October, 1981
163.61-8(7)	Physical State	Yes	Each product	No	—	Yes/October, 1981
163.61-8(8)	Density of Specific Gravity	Yes	Each product	No	—	Yes/October, 1981
163.61-8(9)	Boiling Point	No				

These data requirements are current as of April, 1981. Refer to guidance package for updated requirements.

Table 3 (Cont'd)

Product Chemistry (See Chapter IV)
Ammonium Sulfamate Product-Specific Data Requirements for End-Use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, month's allowed for submission from published date of standard
163.61-8(11)	pH	Yes	Each product	No	—	Yes/October, 1981
163.61-8(12)	Storage Stability	Yes	Each product	No	—	Yes/October, 1981
163.61-8(13)	Flammability	Yes 1/	Each product	No	—	Yes/October, 1981
163.61-8(14)	Oxidizing or Reducing Action	Yes	Each product	No	—	Yes/October, 1981
163.61-8(15)	Explosiveness	Yes 2/	Each product	No	—	Yes/October, 1981
163.61-8(16)	Miscibility	Yes 3/	Each product	No	—	Yes/October, 1981
163.61-8(17)	Viscosity	Yes	Each product	No	—	Yes/October, 1981
163.61-8(18)	Corrosion Characteristics	Yes	Each product	No	—	Yes/October, 1981

1/ Required for products containing a volatile, flammable ingredient.
2/ Required for products containing a potentially explosive ingredient.
3/ Required for products which may be diluted with petroleum solvents.

These data requirements are current as of April, 1981. Refer to guidance package for updated requirements.

Table 3 (Cont'd)

Ammonium Sulfamate Toxicology (See Chapter VI)
Product-Specific Data Requirements for End-Use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
Crystalline Formulations						
163.81-1	Acute Oral Toxicity	Yes[1/]	Each product	No	—	No
163.81-2	Acute Dermal Toxicity	Yes[1/]	Each product	No	—	No
163.81-3	Acute Inhalation Toxicity	Yes[1/]	Each product	No	—	No
163.81-4	Primary Eye[2/] Irritation	Yes[2/]	See footnote 2	No	—	Yes/October, 1981
163.81-5	Primary Dermal[2/] Irritation	Yes[2/]	See footnote 2	No	—	Yes/October, 1981
163.81-6	Dermal[1/] Sensitization	Yes[1/]	Each product	No	—	No

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1/ The testing of the manufacturing-use product will fill these data requirements for crystalline formulations. These requirements will be filled by data required in Table 2 entitled: "Ammonium Sulfamate Toxicology Product - Specific Data Requirements for Manufacturing-Use Products".

2/ This test is required on any one of the products with the following registration numbers: 2169-262, 829-180, 10107-21, 352-206, 8127-22, 1348-202, 829-220, 8590-219, 2125-47, 5481-56, 4887-134.

These data requirements are current as of April, 1981. Refer to guidance package for updated requirements.

Table 3 (Cont'd)

Ammonium Sulfamate Toxicology (See Chapter VI)
Product-Specific Data Requirements for End-Use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
2. Soluble Concentrate						
163.81-1	Acute Oral Toxicity	Yes	Each product	Yes	Bullock and Narcisse 1974a, MRID# 00004214	No
163.81-2	Acute Dermal Toxicity	Yes	Each product	Yes	Bullock and Narcisse 1974b, MRID# 00004215	No
163.81-3	Acute Inhalation Toxicity	Yes[3/]	Each product	No	—	No
163.81-4	Primary Eye Irritation	Yes	Each product	Yes	Bullock and Narcisse 1974d, MRID# 00004216	No
163.81-5	Primary Dermal Irritation	Yes	Each product	Yes	Bullock and Narcisse 1974e, MRID# 00004217	No
163.81-6	Dermal Sensitization	Yes[3/]	Each product	No	—	No

3/ The testing on the manufacturing-use product(s) will fill these data requirements for the soluble concentrate formulations. These requirements will be filled by data required in Table 2 entitled: "Ammonium Sulfamate Toxicology Product - Specific Data Requirements for Manufacturing-Use Products".

These data requirements are current as of April, 1981. Refer to guidance package for updated requirements.

Table 3 (Cont'd)

Ammonium Sulfamate Toxicology (See Chapter VI)
Product-Specific Data Requirements for End-Use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
3. Ready-to-Use						
163.81-1	Acute Oral Toxicity	Yes	Each product	Yes	Bullock and Narcisse 1974a, MRID# 00004214	No
163.81-2	Acute Dermal Toxicity	Yes	Each product	Yes	Bullock and Narcisse 1974b, MRID# 00004215	No
163.81-3	Acute Inhalation Toxicity	Yes[4/]	Each product	No	—	No
163.81-4	Primary Eye Irritation	Yes	Each product	Yes	Bullock and Narcisse 1974d, MRID# 00004216	No
163.81-5	Primary Dermal Irritation	Yes	Each product	Yes	Bullock and Narcisse 1974e, MRID# 00004217	No
163.81-6	Dermal Sensitization	Yes[4/]	Each product	No	—	No

[4/] The testing on the manufacturing-use product(s) will fill these data requirements for the ready-to-use formulations. These requirements will be filled by data required in Table 2 entitled: "Ammonium Sulfamate Toxicology Product-Specific Data Requirements for Manufacturing-Use Products."

These data requirements are current as of April, 1981. Refer to guidance package for updated requirements.

Table 3 (Cont'd)

Ammonium Sulfamate Toxicology (See Chapter VI)
Product-Specific Data Requirements for End-Use Products

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
4. **Pressurized Liquid**						
163.81-1	Acute Oral Toxicity	Yes	Each product	Yes	Bullock and Narcisse 1974a, MRID# 00004214	No
163.81-2	Acute Dermal Toxicity	Yes	Each product	Yes	Bullock and Narcisse 1974b, MRID# 00004215	No
163.81-3	Acute Inhalation Toxicity	Yes[5/]	Each product	No	—	No
163.81-4	Primary Eye Irritation	Yes	Each product	No	—	Yes/October, 1981
163.81-5	Primary Dermal Irritation	Yes[5/]	Each product	Yes	Bullock and Narcisse 1974e, MRID# 00004217	No
163.81-6	Dermal Sensitization	Yes	Each product	No	—	No

[5/] The testing on the manufacturing-use product(s) will fill these data requirements for the pressurized liquid formulations. These requirements will be filled by data required in Table 2 entitled: "Ammonium Sulfamate Toxicology Product-Specific Data Requirements for Manufacturing-Use Products."

These data requirements are current as of April, 1981. Refer to guidance package for updated requirements.

IV

Product Chemistry

Introduction

FIFRA 3(c)(2)(A) requires the Agency to establish guidelines for registering pesticides in the United States. The Agency requires registrants to provide quantitative data on all added ingredients, active and inert, which are equal to or greater than 0.1% of the product by weight.

To establish the composition of products proposed for registration, the Agency requires data and information not only on the manufacturing and formulation processes but also a discussion on the formation of manufacturing impurities and other product ingredients, intentional and unintentional. Furthermore, to assure that the composition of the product as marketed will not vary from the composition evaluated at the time of registration, applicants are required to submit a statement certifying upper and lower composition limits for the added ingredients, or upper limits only for some unintentional ingredients. Subpart D of the Proposed Guidelines (43 FR 29696, July 10, 1978) suggests specific precision limits for ingredients based on the percentage of ingredient and the standard deviation of the analytical method.

In addition to the data on product composition, the Agency guidelines also require data to establish the physical and chemical properties of both the pesticide active ingredient and its formulations. For example, data are needed concerning the identity and physical state of the active ingredient such as melting and boiling point data, ambient vapor pressure and solubility. Data are also required on the properties of the formulated product to establish labeling cautions e.g., flammability, corrosiveness or pesticide storage stability. The Agency uses these data to characterize each pesticide and to determine its environmental and health hazards.

Product Chemistry - Manufacturing-Use Ammonium Sulfamate

Product Chemistry Profile

Ammonium sulfamate is a herbicide with the chemical formula: $N_2H_6SO_3$. The technical product is at least 97% pure, forms colorless plates, and is a non-volatile hygroscopic crystalline solid.

Ammonium sulfamate is very soluble in water and liquid NH_3. It is moderately soluble in glycerol, glycols, and formamide. The melting point of ammonium sulfamate is 131-132°C and it decomposes at 160°C to non-flammable gas.

Technical ammonium sulfamate is a "manufacturing-use product" and is used in formulations as a single active ingredient. There are two formulated products with multiple active ingredients.

The manufacturing impurities which are present in ammonium sulfamate were not reported. The confidential statements of ingredients for about 60 formulated products indicate that, with the exception of two compounds, the inert ingredients are cleared under 40 CFR 180.1001. These two inert ingredients are listed in the Confidential Appendix to this Standard. Registrants of end use products with inert ingredients that have not been cleared in 40 CFR 180.1001 must either remove the ingredient from the product or obtain clearance.

No physical/chemical properties for any of the formulations were reported.

Data Requirements

The data requirements needed to evaluate the continued registration of ammonium sulfamate products to which this Standard applies are listed in Chapter III, Tables 1-3.

Topical Discussions

Corresponding to each of the Topical Discussions listed below is the number of the section in the 'Proposed Guidelines for Registering of Pesticides in the United States' (43 FR 29696, July 10, 1978) which explains the minimum data that the Agency requires in order to adequately assess Product Chemistry of manufacturing-use ammonium sulfamate products. Also, under each of the following topics is a reference to the appropriate section in the 'Proposed Guidelines'.

Chemical Identity	163.61-3
Manufacturing Processes	163.61-4
Formation of Unintentional Ingredients	163.61-5
Active Ingredient Limits in Pesticide Products	163.61-6
Product Analytical Methods and Data	163.61-7
Physical/Chemical Properties	163.61-8

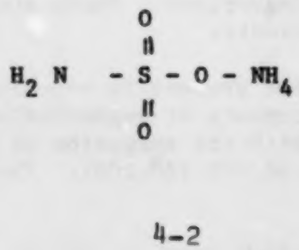
Chemical Identity

The Proposed Guidelines (40 CFR 163.61-3(c)) require identifying information including chemical names, product names, and numerical codes of all substances known or assumed to be present in pesticide products.

Ammonium sulfamate is the accepted name for the chemical. The Weed Science Society of America (WSSA) has adopted the common name 'AMS'. Ammonium sulfamate is also known by the Trade names "Ammate" and "Ikurin". Other names for the chemical listed in the Farm Chemicals Handbook 1980 include: Ancide and Sulfamate. The Chemical Abstracts Registry (CAS) number for ammonium sulfamate is 7773-06-0, and the EPA Shaughnessy number is 005501.

The chemical name ammonium sulfamate will be routinely used in this registration standard in lieu of trade or other names.

The molecular configuration of ammonium sulfamate is:



$$H_2N - \overset{\overset{\displaystyle O}{\|}}{\underset{\underset{\displaystyle O}{\|}}{S}} - O - NH_4$$

Manufacturing Processes

Because the route by which a pesticide is synthesized determines the nature and amount of potentially toxic impurities, a detailed description of the manufacturing process is required (40 CFR 163.61-4).

The open literature describes a number of processes by which ammonium sulfamate may be synthesized:

(A) By neutralization with ammonia of sulfamic acid obtained by careful heating of urea with oleum:

$$(NH_2)CO+SO_3 + H_2SO_4 - 2\ HSO_3NH_2+CO_2$$
$$HSO_3NH_2 + NH_3 - NH_4SO_3NH_2.$$

The yield of ammonium sulfamate by this reaction is said to be not less than 90% with a purity of not less than 90%. (U.S. Patents 2,102,350, and 2,487,480) (MRID# 00160001, 00160002.)

(B) Directly, by reaction of ammonia and sulfuric anhydride at an elevated temperature. The purification is complicated, but the process is inexpensive. (Sitting, Noyes Data Corp., Park Ridge, New Jersey, 1977).

(C) By the action of non-gaseous sulfur trioxide on liquid ammonia. (US Patent 2,426,240) (MRID# 00160003).

(D) By heating ammonium nitrilosulfonate under high pressure, (MRID# 05011074).

(E) By heating imidosulfonate in the presence of ammonia under high pressure (MRID# 05004655).

(F) By a laboratory procedure involving the reaction of ammonia and sulfur dioxide to produce sulfur, ammonium sulfate, and ammonium sulfamate (MRID# 05010475).

The Farm Chemicals Handbook 1980 lists the E.I. du Pont de Nemours and Co., Inc. as the only basic producer of ammonium sulfamate in the United States, which it markets under the Trade name "Ammate". No description of the manufacturing process actually being used by Du Pont has been submitted. This constitutes a data gap.

Ammonium sulfamate is also manufactured abroad. This material is imported by Aceto Chemical Co., but there is no description of this manufacturing process. This constitutes a data gap.

Formation of Unintentional Ingredients

Section 163.61-5 of the Proposed Guidelines required registrants of manufacturing-use and of formulated products to submit a theoretical discussion of the formation of unintended subtances in the product.

No data on the nature of the impurities which may be present in ammonium sulfamate were available. This constitutes a data gap.

Active Ingredient Limits in Pesticides Products

The Guidelines require that upper and lower limits be established for each active ingredient and each intentionally added inert in a pesticide product (40 CFR 163.61-6).

A statement submitted by Du Pont states that its technical grade Ammate contains at least 97% ammonium sulfamate. The remaining 3% consists of manufacturing impurities whose identities have not been reported to the Agency.

Product Analytical Methods and Data

The Proposed Guidelines (40 CFR 163.61-7) require submission of, or reference to, analytical methods for measuring each active ingredient in a pesticide product.

The manufacturer of ammonium sulfamate did not report a method for the identification and quantification of the active ingredient and possible manufacturing impurities in the technical product nor in the end use formulations. This constitutes a data gap.

The EPA Manual of Chemical Methods for Pesticides and Devices reports a method for the determination of ammonium sulfamate by sodium nitrate titration; however, the sensitivity of the method, accuracy and reproducibility are not reported.

Physical and Chemical Properties

For every pesticide product, the Proposed Guidelines (163.61-8) require data on certain physical and chemical properties useful for identification purposes or for evaluation of hazard potential.

Available data from the open literature and registrant submissions on the physical and chemical properties of technical ammonium sulfamate are as follows:

Color: colorless (Technical chemical) (MRID# 05008521)

Odor: There are no available data.

Melting Point: 131°C (Technical chemical) (MRID# 05016316)

Solubility: Very soluble in water (232 gm/100 cc at 30°C), soluble in glycerol, glycols, and formamide. (MRID# 00160004)

Stability: There are no data available.

Octanol/Water Partition Coefficient: There are no data available.

Physical State: Solid crystals (MRID# 05008521)

Density or Specific Gravity: There are no data available.

Vapor Pressure: There are no data available.

pH: For a 5% solution, the pH equals 5.2. (MRID# 05016316)

The following physical/chemical properties were not reported for manufacturing-use ammonium sulfamate:

- Physical State
- Density or Specific Gravity
- pH
- Storage Stability
- Flammability
- Oxidizing or reducing action
- Explosiveness
- Miscibility
- Viscosity
- Corrosion Characteristics
- Dissociation Constant

Product Chemistry - Ammonium Sulfamate End Use Products

No data are available on ammonium sulfamate end-use products. The required data are presented in Chapter III, Table 3.

V

ENVIRONMENTAL FATE

Use Profile

Ammonium sulfamate is an inorganic salt used as a nonselective herbicide on a variety of sites. Registered use sites include:

- Apple and pear orchards
- Pastures
- Rangeland
- Right-of-ways
- Industrial sites (such as farms and railroad switchyards)
- Roadsides
- Landscaped areas (such as lawn borders, walkways and patios)
- Paved areas (such as parking lots and tennis courts)
- Borders of drainage ditches and reservoirs
- Other noncrop areas

Ammonium sulfamate in effective is killing most wood plants including hardwood and coniferous species. It is considered useful for control of poison ivy. Ammonium sulfamate also controls herbaceous perennials such as leafy spurge, bitter dock, goldenrod, perennial ragweed, milkweed, and blueweed, as well as most annual broadleaf weeds and grasses.

About 88% of ammonium sulfamate domestic annual production is used by industry, commercial, or government personnel on the noncrop uses mentioned above. Sites of particular importance in this group are roadsides, and brushy areas along drainage ditches and reservoirs. About 7% of ammonium sulfamate production is applied to agricultural sites, primarily in apple and pear orchards for control of poison ivy. Very little is used on pastures and rangeland. An additional 5% is used by homeowners, mostly for control of weeds in landscaped areas and for control of poison ivy.

Three types of formulation are available: crystals containing 95 to 99% A.I.; soluble liquid concentrates containing 19 to 55% A.I.; and ready-to-use solutions containing from 8 to 12% A.I.

Ammonium sulfamate solutions are applied to target weeds by airblast sprayers, tractor-pulled ground rig, hand-directed sprayers, or backpack and hose-end sprayers. Along waterways, solutions may be applied by boat-mounted spray equipment. Typical right-of-way application is by a boom-type sprayer. Ammonium sulfamate is also applied as dry crystals to notches in undesired trees and to tree stumps to prevent sprouting.

Use rates are 57-120 lbs A.I. in 100 gallons of water per acre for all sprayers except airblast equipment. The recommended rate for airblast equipment is 100-400 lbs A.I. per acre in 100 gallons of water. Ammonium sulfamate is not normally applied with other pesticides nor is it applied aerially. Diesel oil is often used with ammonium sulfamate in dormant stem treatments of weed trees since the oil aids penetration of bark and promotes herbicide entry. Surfactants are also frequently added at the time of application to water-based solutions.

Environmental Fate-Manufacturing-Use Ammonium Sulfamate

Environmental Fate Profile

The submitted data are insufficient to predict the fate of ammonium sulfamate (AMS) in the environment. Preliminary data indicate that AMS may, under certain circumstances, increase or decrease microbial populations in soil. The treatment of starch amended soil with AMS led to an increase and decrease in the number of fungi and bacteria (including actinomycetes), respectively. AMS had no effect on microbial counts obtained from non-amended soil. Fungal colonization of AMS-treated hardwood stumps was enhanced over a 2.5-year period relative to nontreated stumps, indicating that fungal cellulose degradation processes are probably not inhibited by AMS. Limited data on the leaching of AMS indicate that it is very mobile in soil and moves by mass flow. AMS at 50-200 kg/ha will leach about 14 and 15 cm in soil eluted with 2-4 and 50 cm of water, respectively.

Data Requirements

The data requirements needed to evaluate the continued registration of ammonium sulfamate products to which this Standard applies are listed in Chapter III, Table 1.

Topical Discussions

Corresponding to each of the Topical Discussions listed below is the number of the section in the "Proposed Guidelines for Registering Pesticides in the United States" (43 FR 29696, July 10, 1978) which explains the minimum data that the Agency requires in order to adequately assess the environmental fate of a pesticide.

Type of Data	Guideline Section
Physico-Chemical Transformation	163.62-7
Metabolism (Soil, Aquatic and Microbiological)	163.63-8
Mobility	163.62-9
Field Dissipation	163.62-10
Accumulation	163.62-11

PHYSIO-CHEMICAL TRANSFORMATION

Hydrolysis

Hydrolysis data are required to support the registration of each manufacturing-use product and of each formulated end-use product intended for terrestrial, forestry, aquatic, and aquatic impact use patterns.

No data are available on the hydrolysis of ammonium sulfamate.

All studies specified in Section 163.62-7(b) are needed to assess the hydrolysis properties.

Photolysis

A photodegradation study in water is required to support the registration of each formulated end-use product intended for terrestrial (except greenhouse and domestic outdoor), aquatic, and forestry use and for any aquatic impact use which results in direct discharges into the aquatic environment. Such a study is also required to support the registration of each manufacturing-use product which legally could be used to make such an end-use product.

Photodegradation studies on soil surfaces are required to support the registration of all formulated AMS products intended for crop and forestry uses.

No data on the photodegradation of AMS are available.

Data specified in Section 163.62-7(c) are needed to determine the effect of light on AMS. Vapor phase studies are not required since AMS does not have a greenhouse use and re-entry is not a consideration at this time.

METABOLISM

Data on metabolism are required to determine the nature and availability of pesticide residues to rotational crops and to help in the assessment of potential disposal and reentry hazards.

Soil Metabolism

An aerobic soil metabolism study is required to support the registration of each end-use product intended for terrestrial or forestry use, and also to support the registration of each manufacturing-use product which legally could be used to make such an end-use product.

An anaerobic soil metabolism study is required to support the registration of each end-use product intended for field or vegetable crop use, and also that of each manufacturing-use product which legally could be used to make such an end-use product. Aerobic soil metabolism data are not required because ammonium sulfamate is not used for field and vegetable crops.

Two studies (Abumiya 1966, 05013104) (Konnai 1974, 05016686) on the soil metabolism of AMS were reviewed and judged to be invalid.

The requirement for the submission of the above data is currently being reserved, pending the receipt and evaluation of hydrolysis and photodegradation data. The results of these tests will determine what chemical species remain in the environment from ammonium sulfamate use and whether the metabolism study is needed to predict the fate of these species.

Aquatic

An aerobic aquatic metabolism study is required to support the registration of each formulated end-use product intended for aquatic use or for any aquatic impact use which results in direct discharges into the aquatic environment. . Such a study is also required to support the registration of each manufacturing-use product which legally could be used to make such an end-use product.

An anaerobic aquatic metabolism study is required to support the registration of each formulated end-use product intended for aquatic or forestry use which results in direct discharges into the aquatic environment. Such a study is also required to support the registration of each manufacturing-use product which legally could be used to make such an end-use product. The anaerobic soil metabolism study in Section 63.62-8(c) may not be substituted for this study.

The requirement for the submission of the above data is currently being reserved, pending the receipt and evaluation of hydrolysis and photodegradation data. The results of the hydrolysis and photodegradation data will determine if additional testing is required.

Microbiological Metabolism

Data on the effects of microbes on pesticide degradation and the effects of pesticides on microbes are required to support the registration of each formulated end-use product intended for terrestrial (except greenhouse and domestic outdoor), aquatic, and forestry use and for any aquatic impact use which results in direct discharges into the aquatic environment. These data are also required to support the registration of each manufacturing-use product which legally could be used to make such a formulated product.

Microbiological - Effects of Microbes on Pesticides

One study (Frederick 1957, 05011435) on the metabolism of AMS by microbes was reviewed and considered invalid.

The requirement for the submission of the above data is currently being reserved pending the review and modification of the testing protocols. Consequently, the absence of acceptable data does not constitute a data gap.

Microbiological - Effects of Pesticides on Microbes

Two valid studies on the effects of AMS on microbes were reviewed. Smith et al. (MRID 05006452) reported that AMS applied at rates equivalent to 500 and 1,000 lb ai/A had no adverse effects over a 3-week period on fungal, total bacterial, and actinomycete populations in Cadorous silt loam soil. However, AMS treatment of starch-amended soil resulted in an increase in the fungal population and a decrease in total bacterial and actinomycete populations.

Rayner (MRID 05005817) found that AMS treatment of oak, beech, and birch stumps stimulated initial fungal colonization and the subsequent rate of succession on the stumps over a 2.5-year period. These results indicate that fungal cellulose decomposition processes probably are not inhibited by AMS. In summary, the above studies demonstrate that AMS may decrease, and in some cases increase, microbial populations in the environment.

The requirement for the submission of the above data is currently being reserved pending the review and modification of the testing protocols. Consequently, the absence of acceptable data does not constitute a data gap.

Activated Sludge

A laboratory study of the effects of pesticides on the wastewater treatment process is required to support the registration of all manufacturing-use chemicals, and all formulated products that are indirectly discharged into wastewater systems or are used as treatments in wastewater treatment systems.

No data on the activated sludge metabolism of AMS are available.

The requirement for the submission of the above data is currently being reserved pending the review and modification of the testing protocols. Consequently, the absence of acceptable data does not constitute a data gap.

MOBILITY

Data on mobility are required to determine pesticide residue movement in the environment.

Leaching

Leaching data are required to support the registration of each AMS formulated end-use product intended for terrestrial noncrop, tree fruit/nut crop, aquatic, or forestry use, or for any aquatic impact use resulting in direct discharges into the aquatic environment. Such data are also required to support the registration of each manufacturing-use product which legally could be used to make such an end-use product.

Two leaching studies were reviewed and one was considered a scientifically valid study, but does not meet the guidelines requirements because the leaching study was conducted in only one unspecified type of soil. Konnai et al. (MRID 05016686) demonstrated that AMS was very mobile in soil and exhibited a distribution parallel to the mass flow. AMS (95% powder) at 50 kg/ha leached 14 and 50 cm in an unspecified soil type eluted with 2 and 50 cm of water. AMS at 200 kg/ha leached 12-14 cm in a cedar forest soil eluted with only 4 cm of water.

The requirement for the submission of the above data is currently being reserved pending the receipt and evaluation of hydrolysis and photodegradation data. The results of the hydrolysis and photodegradation data will determine what chemical species remain in the environment as a result of ammonium sulfamate use and whether the leaching study is needed to predict the fate of these species.

Volatility

No data are required on the volatility of AMS because the use pattern of AMS does not include a greenhouse use and reentry is not a consideration at this time.

Adsorption/Desorption

A laboratory study using radioisotopic or nonradioisotopic analytical techniques is required to support the registration of all AMS formulated products intended for terrestrial, forestry, and aquatic uses, and for any aquatic impact use which results in direct discharges into the aquatic environment. These data are also required to support the registration of each manufacturing-use product which legally could be used to make such a formulated product.

No data on adsorption/desorption of AMS are available.

The requirement for the submission of the above data is currently being reserved, pending the receipt and evaluation of hydrolysis and photodegradation data. The results of the hydrolysis and photodegradation data will determine what chemical species remain in the environment as a result of ammonium sulfamate use and whether the adsorption/desorption study is needed to predict the fate of these species.

Water Dispersal

A field study tailored to one or more representative sites is required to support the registration of all formulated products intended for aquatic uses, and for any aquatic impact use which results in direct discharges into the aquatic environment. These data are also required to support the registration of each manufacturing-use product which legally could be used to make such a formulated product.

No data on the water dispersal of AMS are available.

The requirement for the submission of the above data is currently being reserved pending the receipt and evaluation of hydrolysis and phtodegradation data.

FIELD DISSIPATION

A field dissipation study under actual use conditions is required to support the registration of all AMS manufacturing-use and formulated products intended for terrestrial (except greenhouses, aquatic, and forestry uses).

Terrestrial

A terrestrial field dissipation study is required to support the registration of each end-use product for terrestrial use (except greenhouses), and that of each manufacturing-use product which legally could be used to make such an end-use product.

No data on the terrestrial field dissipation of AMS are available.

The requirement for the submission of the above data is currently being reserved, pending the receipt and evaluation of hydrolysis and photodegradation data. The results of the hydrolysis and photodegradation data will determine if additional testing is required.

Aquatic

An aquatic field dissipation study is required to support the registration of each AMS formulated end-use product intended for aquatic uses, including products intended for application to ditch banks and shorelines and for unintentional direct aquatic applications, or for any aquatic impact use which results in direct aquatic applications or aquatic impact use with direct discharges into the aquatic environment. This study is also required to support the registration of each AMS manufacturing-use product which legally could be used to make such an end-use product.

One study on the aquatic field dissipation of AMS was reviewed and judged invalid.

The requirement for the submission of the above data is currently being reserved, pending the receipt and evaluation of hydrolysis and photodegradation data. The results of the hydrolysis and photodegradation data will determine if additional testing is required.

Forestry

A forestry study is required to support the registration of each AMS formulated end-use product intended for forest use, and of each AMS manufacturing-use product which legally could be used to make such an end-use product.

No data on the dissipation of AMS in forests are available.

The requirement for the submission of the above data is currently being reserved, pending the receipt and evaluation of hydrolysis and photodegradation data. The results of the hydrolysis and photodegradation data will determine if additional testing is required.

Aquatic Impact Uses

No data are required under this topic for AMS. Required data have been noted under other sections in this chapter.

Combination and Tank Mixes

Data requirements for combination and tank mixes containing AMS are not cited here because this registration standard deals only with the single active ingredient.

ACCUMULATION

Data on accumulation are required to determine accumulation in food webs.

Rotational Crops

No data on the accumulation of AMS in rotational crops are required because the use pattern is such that application to field/vegetable and aquatic food crops will not occur.

Irrigated Crops

No data are required on the accumulation of AMS in irrigated crops because the use pattern indicates that crops are not irrigated with AMS-treated water. At this time AMS would not be expected to contribute significant quantities of AMS to irrigation water.

Fish

A fish accumulation study is required to support the registration of each formulated end-use product intended for outdoor impact use (except domestic outdoor), or aquatic impact uses resulting in direct discharge into aquatic environments, and for each manufacturing-use product that could be legally used to produce such a product. These data are not required if the registrant can offer evidence acceptable to the Agency showing that the applied pesticide and one of its principal degradation product(s):

1. will not reach water, or will not persist in water (i.e., a nominal half-life of four days or less); and

2. has physical properties suggesting a relatively low potential for accumulation (i.e., a nominal octanol/water partition coefficient less than 1000); or

3. does not accumulate in the organs and tissues of mammals or avian species.

The Agency may consider the particular use pattern and the rate and frequency of application in making a decision to waive or maintain the data requirement (such as in cases where movement to water is obviously negligible or where frequent application counteracts a fast dissipation rate).

The requirement for the submission of the above data is currently being reserved, pending the receipt and evaluation of hydrolysis and photodegradation data. The results of the hydrolysis and photodegradation data will determine if additional testing is requried.

Formulations of Ammonium Sulfamate

Three formulations of ammonium sulfamate are available: crystals (95 to 99 % A.I.), soluble liquid concentrates (19 to 54% A.I.), and ready-to-use preparations (8 to 12% A.I.). The formulations are usually applied as a hand-directed spray, although high-volume and airblast sprayers are also used. Use rates are usually 57-120 lbs A.I. in 100 gallons water per acre for all sprayers except airblast equipment, where the recommended rate is 100-400 lbs A.I. per acre in 100 gallons of water.

Although ammonium sulfamate is not applied aerially, the use of airblast machines (which direct the spray upward) increases the potential for exposure via spray drift to humans, livestock or wildlife outside the application site. However, the extent to which air blast machinery is used for application of ammonium sulfamate is not known. Preliminary data indicates that ammonium sulfamate may leach; therefore, the potential for groundwater contamination exists. The potential for surface water contamination exists through the use of ammonium sulfamate for control of willow, cottonwood and other brush along waterways.

As with most pesticides, the greatest human exposure may occur during mixing, loading and treatment operations. However, quantitative data necessary to estimate the degree of such exposure are not available. The potential for dermal and eye exposure from splashing of the soluble liquid concentrate formulation exists, but can be minimized by the use of protective clothing and gloves during mixing and loading. Ready-to-use formulations can be especially important in reducing exposures to small-volume users (i.e., homeowners), because mixing operations are not required.

VI

TOXICOLOGY

Toxicology - Manufacturing-Use Ammonium Sulfamate

Toxicology Profile

No data were available to assess the following toxicity of manufacturing-use ammonium sulfamate: acute oral, acute dermal, acute inhalation, primary eye irritation, primary dermal irritation, and dermal sensitization potential.

Insufficient data were available to assess the subchronic toxicity of manufacturing-use ammonium sulfamate. In a subchronic oral toxicity study conducted on rats using a 99% crystalline formulation of ammonium sulfamate, an 18% weight gain depression was noted in adult females at the high dose (500 mg/kg/day). Histopathological examination of the animals in this group revealed that one rat showed slight fatty degenerative changes in the liver. Lack of individual animal data and inadequate reporting preclude the use of this study to assess the subchronic oral toxicity potential of manufacturing-use ammonium sulfamate in humans.

No adequate subchronic dermal toxicity data were available on manufacturing-use ammonium sulfamate.

Presently, subchronic inhalation testing is not required for the reregistration of manufacturing-use ammonium sulfamate. The Proposed Guidelines state that subchronic inhalation testing is required on manufacturing-use products whose pesticidal use may result in repeated inhalation exposure at a concentration which is likely to be toxic as determined from results of the acute inhalation testing. There is no reason to believe that the present use patterns of ammonium sulfamate will result in repeated inhalation exposure at toxic concentrations. This information may be required pending the results from the acute inhalation testing.

Adequate data were not available on the chronic toxicity of manufacturing-use ammonium sulfamate. A 19-month study was conducted in which rats were fed 0.035% and 0.05% ammonium sulfamate in the diet. No histopathological alterations could be attributed to the ammonium sulfamate in the diet. Sufficient data were not available to evaluate the effects of ammonium sulfamate on any other parameter; therefore, this study cannot be used to assess the chronic toxicity of ammonium sulfamate.

Summary data from a three-generation reproduction study in which rats were fed 0.035% and 0.05% ammonium sulfamate in the diet indicated that no reproductive toxicity was observed through the F_3a generation. This study was inadequately reported because no individual animal data were available and, therefore, an assessment of the reproductive toxicity potential of ammonium sulfamate cannot be made.

No data were available to assess the oncogenic and teratogenic potential of the manufacturing-use ammonium sulfamate.

Adequate metabolism studies were not available for ammonium sulfamate.

Data on the mutagenic potential of ammonium sulfamate in microbial systems were insufficient. No other data were available to assess the mutagenic potential of ammonium sulfamate.

Data Requirements

The data requirements needed to evaluate the continued registration of ammonium sulfamate products to which this Standard applies are listed in Chapter III, Tables 1- 3.

Required Labeling

Precautionary labeling of each product must correspond to the toxicity categories determined by five acute toxicity tests.

Topical Discussions

Corresponding to each of the Topical Discussions listed below is the number of the section(s) in the "Proposed Guidelines" of August 22, 1978 (43 FR, No. 163 37336) which explain(s) the minimum data that the Agency usually requires in order to adequately assess the toxicity of pesticides. Where no section number is listed, a minimum requirement has not been set for such information. Also under each of the topics is a reference to the section in the "Proposed Guidelines".

	Guidelines Section(s)
Acute Oral Toxicity	163.81-1
Acute Dermal Toxicity	163.81-2
Acute Inhalation Toxicity	163.81-3
Primary Eye Irritation	163.81-4
Primary Dermal Irritation	163.81-5
Skin Sensitization	163.81-6
Acute Delayed Neurotoxicity	163.81-7
Subchronic Oral Toxicity	163.82-1
Subchronic 21-Day Dermal Toxicity	163.82-2
Subchronic 90-Day Dermal Toxicity	163.82-3
Subchronic Inhalation Toxicity	163.82-4
Subchronic Neurotoxicity	163.82-5
Chronic Feeding	163.83-1
Oncogenicity	163.83-2
Teratology	163.83-3
Reproduction	163.83-4
Mutagenicity	163.83-1 to 4
Metabolism in Laboratory Animals	163.83-1
Clinical Trials	
Emergency Treatment	

Acute Testing

Acute Oral Toxicity

The minimum data requirement for testing acute oral toxicity (LD_{50}) is one test on the manufacturing-use product, preferably using the laboratory rat.

No acute oral toxicity studies are available on manufacturing-use ammonimum sulfamate. Testing is required.

Acute Dermal Toxicity

The minimum data requirement for testing acute dermal toxicity is one test, preferably in the albino rabbit, on each manufacturing-use product.

No acute dermal toxicity tests on manufacturing-use ammonium sulfamate are available. Testing is required.

Acute Inhalation Toxicity

Acute inhalation testing is required to support the registration of the manufacturing-use and formulated products if: the product is a gas, the product produces a respirable vapor or 20% or more of the aerodynamic equivalent of the product is composed or particles not larger than 10 microns. Testing in the laboratory rat is preferred.

The use pattern indicates that ammonium sulfamate is used by a route that could permit inhalation exposure (i.e. used as a spray for weed control). Since no information is available to assess the aerodynamic size of the particles or the vapor pressure of ammonium sulfamate, acute inhalation testing is required.

No acute inhalation toxicity studies are available on manufacturing-use ammonium sulfamate. Testing is required.

Primary Eye Irritation

The minimum data requirement for primary eye irritation is one test on each manufacturing-use product, preferably using the albino rabbit. If the test substance has a pH of 1-3 or 12-14, it will be judged corrosive, and an eye irritation test is not needed. Also, if the test substance has been judged to be dermally corrosive, an eye irritation test is not needed.

No primary eye irritation studies are available on manufacturing-use ammonium sulfamate. Testing is required.

Primary Dermal Irritation

The minimum data requirement for primary dermal irritation is one test on each manufacturing-use product, preferably using the albino rabbit.

No primary dermal irritation studies are available on manufacturing-use ammonium sulfamate. Testing is required.

Dermal Sensitization

The minimum data requirement for dermal sensitization is an intradermal test on each manufacturing-use product, preferably using the guinea pig.

No dermal sensitization studies are available on manufacturing-use ammonium sulfamate. Testing is required.

Acute Delayed Neurotoxicity

The minimum data requirement for acute delayed neurotoxicity is one test on the manufacturing-use product, using the adult hen.

An acute delayed neurotoxicity test is required if the active ingredient, or any of its metabolites, degradation products, or impurities causes esterase depression or is structurally related to a substance that induces delayed neurotoxicity.

There are no indications that ammonium sulfamate causes esterase depression or is structurally related to known neurotoxins. Therefore, testing is not required.

Subchronic Testing

Subchronic Oral Toxicity

The minimum data requirement for subchronic oral toxicity is one test on the manufacturing-use product in two mammalian species, preferably using the rat and dog.

No adequate subchronic oral toxicity data are available on manufacturing-use ammonium sulfamate. However, a supplementary subchronic oral toxicity study is available on ammonium sulfamate in rats. In this study (Gupta et al. 1979, MRID 05014167), groups of adult female rats and male and female weanling rats were given ammonium sulfamate (crystalline, 99% purity) at 100, 250 or 500 mg/kg orally in an aqueous solution 6 days a week for 90 days.

At the high dose an 18% weight gain depression was observed in the adult female, and histological examination revealed that one animal in this group showed slight fatty degenerative changes in the liver. No individual animal data were included; and therefore, this study is not adequate to evaluate the subchronic toxicity of the chemical. Additional subchronic oral toxicity testing in rats and dogs is required.

Subchronic 21-Day Dermal Toxicity

The minimum data requirement for subchronic 21-day dermal toxicity is one study on the manufacturing-use product, preferably using the albino rabbit. A subchronic 21-day dermal toxicity test is required if pesticidal use is likely to result in repeated human skin contact. Since the use of ammonium sulfamate is likely to result in repeated human skin contact, testing is required.

One subchronic dermal toxicity study was conducted on an unspecified formulation of ammonium sulfamate (Aoyama 1975, MRID 05005119). In this study, 0.75 ml of 15% , 20%, and 30% concentrations of ammonium sulfamate were applied to the unshaved skin of rats, and .75 ml of 15% and 30% concentrations of the chemical were applied to the shaved skin of rabbits daily for 20 days. No deaths were observed in rats or rabbits, and only slight redness of the skin was noted in rats at the highest dose at 7 days. Upon histopathological examination, slight atrophy of the epidermis was observed in rabbits. This study does not satisfy the data requirements for subchronic dermal toxicity testing because too few rabbits were tested, and more than one route of exposure was possible since the application sites were not covered. Additional 21-day dermal toxicity testing is required.

Subchronic 90-Day Dermal Toxicity

A subchronic 90-day dermal toxicity test is not required because ammonium sulfamate is not purposely applied to skin, and its use will not result in human exposure comparable to that, for example, from swimming pool additives or pesticide-impregnated fabrics.

Subchronic Inhalation Toxicity

A subchronic inhalation study is required if pesticidal use may result in repeated inhalation exposure at a concentration that is likely to be toxic, as determined from results of acute inhalation testing. A determination of the requirement for a subchronic inhalation toxicity study of ammonium sulfamate cannot be made at present, because no adequate acute inhalation toxicity data are available.

Subchronic Neurotoxicity

A subchronic neurotoxicity study is not required on ammonium sulfamate, because it is not expected to induce neuropathy or delayed neurotoxicity, and because it does not have a molecular structure closely related to that of a compound that is known to induce neuropathy or delayed neurotoxicity.

Chronic Feeding

A chronic feeding study is required if pesticidal use requires a tolerance or exemption from a tolerance, requires an issuance of a food additive regulation or is likely to result in repeated human exposure over a significant portion of the life-span.

A tolerance exists for ammonium sulfamate on apples and pears; however, ammonium sulfamate is not applied directly to the fruits since it is used for weed control in these orchards. If the requested residue data (Chapter III, Table 1) shows that negligible residues of ammonium sulfamate and its metabolites are present on raw agriucltural commodities and the environmental fate data indicates that repeated human exposure by other routes is unlikely, this data requirement will be waived.

The available data were inadequate to assess the chronic feeding effects of ammonium sulfamate. In a 19-month feeding study with rats (Sherman et al., 1964 MRID #00004224), no histopathological alterations could be attributed to the feeding of .035% and .05% ammonium sulfamate in the diet. Sufficient data were not available to evaluate the effects of ammonium sulfamate on any other parameter, therefore, an adequate assessment of the chronic toxicity of ammonium sulfamate cannot be made from this data.

Oncogenicity

Oncogenicity tests on the manufacturing-use product are required in two mammalian species, preferably the rat and the mouse, for all food uses. A tolerance exists for ammonium sulfamate on apples and pears; however, ammonium sulfamate is not applied directly to the fruits since it is used for weed control in these orchards. If requested residue data (Chapter III, Table 1) shows that negligible residues of ammonium sulfamate and its metabolites are present on raw agricultural commodities and the environmental fate data indicates that repeated human exposure by other routes is unlikely, this data requirement may be waived.

Teratogenicity

The minimum requirement for evaluating a pesticide for teratogenicity is testing in two mammalian species. Teratogenicity testing is required on ammonium sulfamate because it is registered for domestic use and may be expected to result in significant exposure to human females. No data were available to evaluate the teratogenicity potential of ammonium sulfamate. Testing is required in two mammalian species.

Reproduction

The minimum data requirement for reproduction is testing in one mammalian species, preferably the laboratory rat, using the manufacturing-use product and lasting for two generations. This is required for all food uses. No adequate studies assessing the effects of ammonium sulfamate on reproduction are available at this time. A rat reproduction study (Sherman et al. 1964, MRID 00004224) containing summary data only, is in the Agency files. In this study, rats were fed 0.035% and 0.05% ammonium sulfamate in the diet through the F_3a generation. No consistent toxic effects were observed on growth, reproductive performance, viability, or lactation, and no abnormal histopathological findings were reported by the authors in summary form. The requirement for additional reproduction testing may be waived if adequate residue data show that negligible residues of ammonium sulfamate and its metabolites are present in raw agricultural commodities and adequate environmental fate data indicates that repeated human exposure by other routes is unlikely, this data requirement may be waived.

Mutagenicity

The following studies represent the minimum data likely to be required on the potential heritable effects of ammonium sulfamate:

1. A mammalian in vitro point mutation test.
2. A sensitive sub-mammalian point mutation test (Bacteria, fungi, insect).
3. A primary DNA damage test (i.e., sister chromatid exchange or unscheduled DNA synthesis).
4. A mammalian in vitro cytogenics test. If this suggests a positive result, a dominant lethal or heritable translocation test may be required.

After results from these test systems and other toxicology disciplines have been considered, additional testing may be required to further characterize or quantify the potential genetic risks.

Although the Agency mutagenic testing requirements are not final, the standards for these tests should be based on the principles set forth in FR 43, No. 163, August 22, 1978. Protocols and choices of test systems should be accompanied by a scientific rationale. Substitution of test systems for those listed above will be considered after discussion with the Agency.

A supplementary study is available in which an unspecified formulation of ammonium sulfamate was evaluated for its ability to produce point mutations in histidine requiring mutants of Salmonella typhimurium (Anderson et al. 1972, MRID 05001460). Negative results were observed with ammonium sulfamate while positive responses were produced with three known mutagens. No numerical data were available for the positive controls; therefore, the reliability of the assay cannot be determined. Thus, the minimum mutagenicity data requirements for ammonium sulfamate have not been fulfilled and additional testing as specified above is required.

Metabolism in Laboratory Animals

A general metabolism study is required to support the registration of each manufacturing use product which requires a chronic feeding study or an oncogenicity study.

No adequate metabolism study is available on ammonium sulfamate. An assessment of this data requirement cannot be made at the present time, because the need for the chronic feeding or oncogenicity data is not yet established.

Clinical Trials

No clinical studies in humans have been conducted using ammonium sulfamate.

Emergency Treatment

No information is available on emergency treatment of ammonium sulfamate poisoning.

Toxicology - Crystalline Ammonium Sulfamate

Toxicology Profile

No data were available to assess the acute oral, acute dermal,and acute inhalation toxicity of crystalline formulations containing 95-99% ammonium sulfamate. Testing is not required since testing of the manufacturing-use product will be sufficient to evaluate the acute toxicities of these products.

No data were available to evaluate the primary eye irritation, primary dermal irritation and dermal sensitization potentials of ammonium sulfamate. Dermal and eye irritation testing is required on any one of the products listed in Chapter III, Table 3. These products contain an inert ingredient that may cause dermal and eye irritation.

Dermal sensitization testing is not required since testing of the manufacturing-use product will be sufficient to fulfill this requirement.

Data Requirements

The data requirements needed to evaluate the continued registration of ammonium sulfamate products to which this Standard applies are listed in Chapter III, Tables 1-3.

Topical Discussions

Acute Testing

Acute Oral Toxicity

The minimum data requirement for testing acute oral toxicity (LD_{50}) is one test in the laboratory rat on each formulated crystalline product.

No acute oral toxicity studies are available on crystalline formulations of ammonium sulfamate. Testing on manufacturing-use ammonium sulfamate will fill this requirement.

Acute Dermal Toxicity

The minimum data requirement for testing acute dermal toxicity is one test on each formulated crystalline product, preferably using the albino rabbit.

No acute dermal toxicity studies are available on crystalline formulations of ammonium sulfamate. Testing on manufacturing-use ammonium sulfamate will fill this requirement.

Acute Inhalation Toxicity

The minimum data requirement for testing acute inhalation toxicity (LC_{50}) is one test on each formulated crystalline product, preferably using the laboratory rat.

No acute inhalation toxicity studies are available on crystalline formulations of ammonium sulfamate. Testing on manufacturing-use ammonium sulfamate will fill this requirement.

Primary Eye Irritation

The minimum data requirement for primary eye irritation is one test on each formulated crystalline product, preferably using the albino rabbit.

No primary eye irritation studies are available on crystalline formulations. Testing is required on one of the products with the following registration numbers: 2169-262, 829-180, 10107-21, 352-206, 8127-22, 1348-202, 829-220, 8590-219, 2125-47, 5481-56, 4887-134.

Primary Dermal Irritation

The minimum data requirement for primary dermal irritation is one test on each formulated crystalline product, preferably using the albino rabbit.

No primary dermal irritation studies are available on crystalline formulations. Testing is required on one of the products with the following registration numbers: 2169-262, 829-180, 10107-21, 352-206, 8127-22, 1348-202, 829-220, 8590-219, 2125-47, 5481-56, 4887-134.

Dermal Sensitization

The minimum data requirement for dermal sensitization is an intradermal test on each formulated crystalline product, preferably using the guinea pig.

No dermal sensitization studies are available on crystalline formulations of ammonium sulfamate. Testing on manufacturing-use ammonium sulfamate will fill this requirement.

Toxicology - Soluble Concentrate Ammonium Sulfamate

Toxicology Profile

Sufficient data are available to assess the acute oral and dermal toxicities of a soluble concentrate formulation containing 43% ammonium sulfamate. The high acute oral LD_{50} in rats (male rats, 6.9 g/kg; female rats, 3.9 g/kg) indicates a potentially low acute oral toxicity in humans. A high acute dermal LD_{50} in rabbits (greater than 2 g/kg) with this formulation, indicates a potentially low acute dermal toxicity in humans.

An acute inhalation toxicity study conducted with rats using a 43% ammonium sulfamate soluble concentrate formulation is available. However, since the exposure concentration and the particle size distribution were inadequately described, the study cannot be used to assess the potential acute inhalation toxicity of this formulation in humans.

Data are available to assess the primary eye irritation and primary dermal irritation potentials of a 43% ammonium sulfamate soluble concentrate formulation. These data indicate that this formulation is not a primary eye irritant but may cause transient eye irritation in humans, also, the data indicate a low dermal irritation potential in humans. No data were available to assess the dermal sensitization potential of the soluble concentrate formulations.

Data Requirements

The data requirements needed to evaluate the continued registration of ammonium sulfamate products to which this standard applies are listed in Chapter III, Tables 1-3.

Topical Discussions

Acute Testing

Acute Oral Toxicity

The minimum data requirement for testing acute oral toxicity (LD_{50}) is one test on each formulated soluble concentrate product, preferably using the laboratory rat.

An adequate acute oral toxicity study in rats is available with a soluble concentrate containing 43% ammonium sulfamate (Bullock and Narcisse, 1974a, MRID 00004214). The undiluted material was administered by gavage to four groups of male and female rats. The LD_{50} in males was 6.9 g/kg with a 95% confidence interval of 2.6-18.3 g/kg. In females the LD_{50} was 3.9 g/kg with a 95% confidence interval of 2.0-7.6 g/kg. No adverse clinical signs were observed in females receiving the lowest dose (1.9 g/kg). Slight depression was observed in males receiving 2.8 g/kg. Signs of toxicity in animals receiving the higher dose levels included depression, salivation, bloody tears, and collapse. All deaths, 7 males and 8 females, occurred within 24 hours of dosing. The survivors (12 males and 13 females) showed no chemical-related gross pathological changes.

These data are sufficient to fulfill the acute oral toxicity data requirement for the existing soluble concentrate formulations containing 19-55% ammonium sulfamate and place these products in Toxicity Category III.

Acute Dermal Toxicity

The minimum data requirement for testing acute dermal toxicity (LD_{50}) is one test on each formulated soluble concentrate product, preferably using the albino rabbit.

An adequate acute dermal toxicity study is available with a soluble concentrate containing 43% ammonium sulfamate (Bullock and Narcisse 1974b, MRID 00004215). In this study the acute dermal LD_{50} in male New Zealand albino rabbits was determined to be greater than 2 g/kg. No mortality was observed when six males were administered 2 g/kg of the undiluted material under an occlusive wrap; half of the animals had abraded skin, and half had intact skin. At 24 hours slight to severe erythema was observed but there were no other signs of toxicity during the 14-day observation period. Although only males were tested, the study is sufficient to fulfill the acute dermal toxicity data requirement for the existing soluble concentrate formulations containing 19-55% of ammonium sulfamate. The data place these products in Toxicity Category III.

Acute Inhalation Toxicity

Acute inhalation testing is required to support the registration of formulated products if: the product is a gas, the product produces a respirable vapor or

20% or more of the aerodynamic equivalent of the product is composed of particles not larger than 10 microns. Testing in the laboratory rat is preferred.

An acute inhalation toxicity study (Bullock and Narcisse, 1974c, MRID# 00004218) was conducted with a 43% soluble concentrate formulation of ammonium sulfamate in rats. This study was inadequate to assess the inhalation toxicity of this formulation.

Based on information in the Confidential Statement of Formulations (CSF's) for the soluble concentrates containing 19-55% ammonium sulfamate, the inert ingredients used in these products are not anitcipated to present problems with respect to inhalation toxicity. Therefore, acute inhalation toxicity testing on the manufacturing-use product will fill this data requirement for the soluble concentrate formulations.

Primary Eye Irritation

The minimum data requirement for primary eye irritation is one test on each formulated product, preferably using the albino rabbit.

An adequate primary eye irritation study is available with a soluble concentrate formulation containing 43% ammonium sulfamate. (Bullock and Narcisse 1974d, MRID 00004216). Instillation of 0.1 ml of the undiluted test material into the conjunctival sac of one eye of each of six rabbits (three males, three females) caused slight to moderate conjunctival irritation in all of the treated eyes. By 72 hours this condition had cleared in all but one animal who still had slight irritation. No corneal opacity or iritis was observed in any of the treated eyes, and by 7 days all the eyes were normal. The data are sufficient to fulfill the primary eye irritation data requirements for the existing soluble concentrate formulations containing 19-55% ammonium sulfamate and place these products in Toxicity Category III, indicating a low potential for eye irritation.

Primary Dermal Irritation

The minimum data requirement for primary dermal irritation is one test on each formulated product, preferably using the albino rabbit.

An adequate primary dermal irritation study is available with a soluble concentrate formulation containing 43% ammonium sulfamte (Bullock and Narcisse 1974e, MRID 00004217). In this study, the product was applied undiluted to the abraded and intact skin of six New Zealand rabbits and the primary skin irritation score was determined to be 0.6 out of a possible 8.0 score. This study is sufficient to fulfill the primary dermal irritation potential data requirement for the existing soluble concentrate formulations containing 19-55% ammonium sulfamate. These products should not be considered primary skin irritants and should be placed in Toxicity Category IV.

Dermal Sensitization

The minimum data requirement for dermal sensitization is an intradermal test on each formulated product, preferably using the guinea pig.

No dermal sensitization studies are available on soluble concentrate formulations of ammonium sulfamate. Based on information in the Confidential Statement of Formulations (CSF's) for the soluble concentrate formulations containing 19-55% ammonium sulfamate, the inert ingredient used in these products are not expected to present a problem with respect to dermal sensitization. Therefore, dermal sensitization testing on the manufacturing-use product will fill this data requirement.

Toxicology Ready-to-Use and Pressurized Liquid Ammonium Sulfamate

Toxicology Profile

No data were available to assess the acute oral, acute dermal, and acute inhalation toxicity as well as the primary eye irritation, primary dermal irritation, and the dermal sensitization potential of the ready-to-use formulations containing 8-55% ammonium sulfamate and the pressurized liquid formulations containing 9.5% ammonium sulfamate.

The Confidential Statements of Formulations (CFS) do not indicate that the acute toxicities (oral, dermal, inhalation), or the eye irritation, dermal irritation and dermal sensitization potentials of the ready-to-use products will differ from those observed with the soluble concentrates. Therefore, refer to the Toxicology Profile and Topical Discussions for soluble concentrate formulations, for an assessment of these toxicity parameters.

Data on the soluble concentrate formulations will fill the following requirements for ready-to-use formulations: acute oral toxicity, acute dermal toxicity, primary eye irritation and primary dermal irritation. Data on the manufacturing-use product will fill the toxicity and dermal sensitization data requirements.

The Confidential Statements of Formulations (CFS) does not indicate that the acute toxicities or the dermal irritation or the dermal sensitization potentials for the pressurized liquid product will differ from those observed with the soluble concentrates.

Therefore, data on the soluble concentrate formulations will fill the following requirements for the pressurized liquid formulation: acute oral toxicity, acute dermal toxicity, and primary dermal irritation. Data on the manufacturing-use product will fill the requirement for acute inhalation toxicity and dermal sensitization for the pressurized liquid.

The pressurized liquid product may have eye irritation properties different from those of the soluble concentrates. Therefore, primary eye irritation testing is required.

Data Requirements

The data requirements needed to evaluate the continued registration of ammonium sulfamate products to which this standard applies are listed in Chapter III, Tables 1-3.

VII

Residue Chemistry

Residue Chemistry - Manufacturing-Use Ammonium Sulfamate

Residue Chemistry Profile

Ammonium sulfamate is used as a herbicide for the control of woody plants, particularly poison ivy.

No data on the metabolism or breakdown patterns of ammonium sulfamate in plants or animals are currently available. There is some indication in the literature that ammonium sulfamate can hydrolyze in the soil to form ammonium sulfate. Additional data are needed showing the nature of any major residues resulting from the applied use of ammonium sulfamate as a result of application to the plants at the tree roots. Similarly, data are needed showing the nature of major residues when ingested by grazing cattle or dairy cows from cover crops in apple or pear orchards, pastures and rangelands that have been treated with ammonium sulfamate, or apple pomace used in feed.

The results from method trials conducted by FDA on the residue analytical methods submitted by the manufacturer were unsatisfactory. Two residue studies were submitted. The studies showed that residues of ammonium sulfamate per se, resulting from certain applications on ten tests with apples and one on pears, did not exceed the established tolerances for apples and pears. However, these test summations were submitted without supporting hard data and were conducted several years prior to the FDA analytical method trials.

There are no records of regulatory incidents or actions with respect to the registered uses of ammonium sulfamate.

Data Requirements

The data required to support the registered food use and tolerances for ammonium sulfamate are presented in Chapter III, Table 1.

Topical Discussions

Use Patterns and Restrictions

Ammonium sulfamate is used as a herbicide primarily for control of woody plants and herbaceous perennials. It is considered especially useful for the control of poison ivy in apple and pear orchards when applied as a foliage spray. The use of ammonium sulfamate in apple and pear orchards is considered to be a food use due to the possibility of residues on the fruit through absorption and translocation or from a contaminative source.

The formulation type and percent active ingredient used in apple and pear orchards are: 95-99% a.i. crystalline and 19-54% soluble concentrate.

The recommended use is 1-3 treatments per growing season (every 6 to 8 weeks) when poison ivy plants are in full leaf. The type of application is foliar drench or hand directed by using either a backpack or ground rig high volume sprayer. The application rate is 57 lbs. A.I. in 100 gal. water. The spray volume depends on the density and size of the poison ivy plants but usually 1 gallon will cover 200-250 sq. ft. of surface.

Present use restrictions include:

Do not spray fruit tree foliage.
Do not spray green or immature fruit tree bark.
Avoid excessive wetting of fruit tree bark.
Use coarse spray.

Metabolism in Plants

Ammonium sulfamate is known to be non-selective and translocates readily. One study on its translocation (Carvell 1955, 05005498) showed that ammonium sulfamate moves into the leaves of plants more rapidly that it moves down into the root system.

No data are available on the metabolic fate of ammonium sulfamate in plants or on residues in plants or trees.

Metabolism in Animals

No studies are available regarding the metabolic fate of ammonium sulfamate residues in large animals.

Analytical Methodology

The accepted method for the determination of ammonium sulfamate in apples and pears is that of H.L. Pease (Pease 1957, 00004228, 05003443, 00004232). This method could not be made to work adequately in government laboratory tests; adequate validation data and data in support of the claimed sensitivity of 0.1 ppm are not presented. Therefore, an adequate analytical method is required.

Residue Data: Apples and Pears

The available residue data for ammonium sulfamate (DuPont 1960, 00004229) is a summary report of two tests conducted from 1957 to 1960, prior to method trials.

The first test consisted of a series of trials conducted in three states using ammonium sulfamate under apple and pear trees. Ammonium sulfamate was used in doses from 0.3 to 1 lb. per tree at 28 to 122 day intervals between treatment and harvest. Residues in ten samples of fruit ranged from 0.1 ppm to 0.6 ppm.

The second test examined residues from applications of ammonium sulfamate for three successive years to soil under apple trees applied at two rates: 1.2 lbs/tree and 6 lbs/tree. Residues ranged from 1.5 to 2.5 ppm and 2.7 to 6.1 ppm from the higher rate.

The limited residue data and the inadequacy of the data collection method do not permit a conclusion that the registered tolerance of 5 ppm is adequately supported.

Residue Data: Meat and Milk

Consideration should be given to the possibility of cattle grazing in fruit orchards, pastures and rangelands treated with ammonium sulfamate, and to the agricultural practice of feeding apple pomace to cattle, including dairy animals. No residue studies were reported for the indicated feed uses. These data requirements are being reserved pending the receipt and evaluation of residue data on apples to determine if residues of ammonium sulfamate are present in cattle and dairy animal feedstuff at a detectable level. Also, residue data on milk and meat are being reserved pending the receipt and evaluation of environmental fate data. Milk and meat residue data may be required if the fate data indicate that use of ammonium sulfamate in fruit orchards, pastures, and rangelands could result in exposure to grazing animals and residues in meat and milk.

VIII

Ecological Effects Chapter

Manufacturing-Use Ammonium Sulfamate

Ecological Effects Profile

No adequate data are available to assess the toxicity of ammonium sulfamate to terrestrial and aquatic organisms.

Supplementary data indicate that toxicity to aquatic organisms is probably low. One study (Matida et al., 1975, 05010743) was conducted by dripping a 70 % a.i. solution of ammonium sulfamate into an artificial stream containing rainbow trout. No adverse effects were noted at concentrations up to 30 ppm. Another study (Eddleman 1974, 05008669) conducted with a 43% a.i. formulated product on Chaoborus punctipennis, the phantom midge, yielded 48-hour LC_{50} values of 6096 ppm and 3183 ppm at 15°C and 20°C respectively. These toxicity values indicate this particular product is practically non-toxic to aquatic invertebrates.

One adequate beneficial insect study was conducted (Atkins et al. 1969, 00018842) in which honey bees were exposed to a mixture of technical ammonium sulfamate and pyrolite dust. The study provided sufficient information to characterize ammonium sulfamate as relatively non-toxic to honey bees (LD_{50} value is greater than 60.43 micrograms/bee).

Available data on the toxicity of ammonium sulfamate to terrestrial and aquatic plants indicate that a temporary phytotoxic effect on turf may occur at application rates of 2.18 lbs. a.i./acre, and aquatic plants may suffer growth reduction if the concentration in the aquatic environment were to reach approximately 1000 ppm.

Data Requirements

The data requirements needed to evaluate the continued registration of ammonium sulfamate products to which this Standard applies are listed in Chapter III, Table 1.

Topical Discussions

Corresponding to each of the Topical Discussions listed below is the number of the section(s) in the Proposed Guidelines of July 10, 1978 (43 FR No. 132, 29696) which explain(s) the minimum data that the Agency requires to adequately assess the effects of ammonium sulfamate to fish and wildlife.

	Guidelines Section
Birds	163.71-1, 163.71-2
Fish	163.72-1
Aquatic Invertebrates	163.72-2

Birds

Birds may be exposed to pesticides by feeding on contaminated plants or insects, by dermal contact and/or inhalation when close to outdoor sprays and dust. To assess the impact of a pesticide on birds, the Agency requires certain avian toxicity tests to support the registration of pesticides.

A determination of the avian acute single-dose oral LD_{50} is required to support the registration of every manufacturing-use product and formulated product for outdoor application. Information regarding the acute toxicity of ammonium sulfamate to birds is not available.

A determination of the subacute dietary LC_{50} (5-day dietary exposure) is also required to support the registration of all manufacturing-use products and all formulated products intended for outdoor application. Testing shall be performed on two avian species, one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably the bobwhite quail).

One study on quails (Maki 1973, GS0016-0020) was submitted and reviewed for this topic. The study was determined invalid. The study contained data from a secondary source, the study protocol and the determination of the LC_{50} was not reported, and the species of quail was not reported. Therefore, no acceptable data on technical ammonium sulfamate are available on this topic and a data gap exists.

Fish

Freshwater Fish

The minimum data required for establishing the acute toxicity of manufacturing-use ammonium sulfamate for fish is a determination of the 96-hour LC_{50} for a coldwater species (preferably rainbow trout) and a warmwater species (preferably bluegill sunfish). No acceptable data on technical ammonium sulfamate are available on this topic and, therefore, a data gap exists.

Matida (1975, 05010743) provides supplemental information for coldwater fish (rainbow trout). This study does not fulfill the guideline requirements for toxicity studies for coldwater fish. In this study, rainbow trout, in an artificial stream situation, showed no adverse effects to concentrations up to 30 ppm of ammonium sulfamate.

There is no requirement for an artificial stream test in the guidelines. Various field studies on an artificial ecosystem study can be requested if the required data indicate that the pesticide poses an environmental threat. These additional data requests are decided on a case-by-case basis.

Aquatic Invertebrates

An acute toxicity LC_{50} test with the technical product on an aquatic invertebrate is required to support registration of all manufacturing-use products and all formulated products intended for outdoor applications. No study on this topic was received and, therefore, the requirement for the technical product has not been satisfied.

Aquatic Plants

One study was available (Fromm 1949, 05004558) concerning the effects of ammonium sulfamate on aquatic plants. The study showed that when Spirodela was grown in a nutrient solution, ammonium sulfamate at 1140 ppm caused a decrease in the number of fronds per plant, even though the number of plants increased temporarily. Therefore, some aquatic plants would be expected to suffer growth reduction if the concentration in the aquatic environment were to reach approximately 1000 ppm.

This type of data is not currently required for registration.

Terrestrial Plants

Acceptable data are available on the toxicity of ammonium sulfamate to terrestrial plants. The information is summarized in the following table:

Table 1: Toxicity of Ammonium Sulfamate To Terrestrial Plants

Species	Formulation	No Effect Level	Author/Date	MRID#
Turfgrass	A.I.	<2.18 lbs/A	Pridham,1946	05004926
Eggplant	A.I.	<100 ppm	Dubey, 1977	05004270
Bean	A.I.	1140 ppm	Fromm, 1949	05004558

Ammonium sulfamate can be expected to have a temporary phytotoxic effect on turf at an application rate of 2.18 lbs a.i./acre. Since ammonium sulfamate is used as a non-selective herbicide on areas where a complete vegetation kill is desired, it seems unlikely that this chemical would be used in areas where it would significantly damage non-target plants.

This type of data is not currently required for registration.

Beneficial Insects

An acceptable study (Atkins et al. 1969, 00018842) on the toxicity of ammonium sulfamate to beneficial insects is available. There is sufficient information to characterize ammonium sulfamate as relatively non-toxic to honey bees, when bees are exposed to a mixture of technical ammonium sulfamate and pyrolite dust (LD50 60.43 micrograms/bee).

This type of data is not currently required for registration.

Crystalline Ammonium Sulfamate

Ecological Effects Profile

The toxicity of crystalline ammonium sulfamate to wildlife may be estimated from tests on the technical chemical.

Topical Discussions

See the Manufacturing-use Ammonium Sulfamate section of this chapter and Chapter III, Table 1 for the ecological effects data requirements to support the registration of ammonium sulfamate formulated products.

The use patterns and formulations currently under consideration do not indicate the need for acute fish and wildlife tests using the formulated products. The toxicity of various formulations and the subsequent hazard to wildlife can be estimated by using the toxicity data provided by tests on the technical chemical.

Soluble Concentrate Ammonium Sulfamate

Ecological Effects Profile

The toxicity of soluble concentrate ammonium sulfamate formulations to wildlife may be estimated from tests on the technical chemical.

Topical Discussions

See the Manufacturing-Use Ammonium Sulfamate section of this chapter and Chapter III, Table 1 for the ecological effects data required to support the registration of ammonium sulfamate formulated products.

The use patterns and formulations currently under consideration do not indicate the need for acute fish and wildlife tests using the formulated products. The toxicity of various formulations and the subsequent hazard to wildlife can be estimated by using the toxicity data provided by tests on the technical chemical.

Freshwater Fish

A study (Matida et al., 1975, 05010743) was done by dripping a 70% soluble concentrate formulation of ammonium sulfamate into an artificial stream containing rainbow trout. No adverse effects were noted at concentrations up to 30 ppm.

Aquatic Invertebrates

One available study (Eddleman 1974, 05008669) was conducted with a 43% soluble concentrate ammonium sulfamate formulation on *Chaoborus punctipennis* (the phantom midge). The 48-hour LC_{50} values at 15°C and 20°C were 6096 ppm and 3183 ppm. These toxicity values indicate that this formulated product is practically non-toxic to aquatic invertebrates.

Ready-to-Use and Pressurized Liquid Ammonium Sulfamate

Ecological Effects Profile

The toxicity of ready-to-use and pressurized liquid formulations to wildlife may be estimated from tests on the manufacturing-use product.

Topical Discussions

See the Manufacturing-Use Ammonium Sulfamate section of this chapter and Chapter III, Table 1 for the ecological effects data required to support the registration of ammonium sulfamate formulated products.

The use patterns and formulations currently under consideration do not indicate the need for acute fish and wildlife tests using formulated products. The toxicity of various formulations and the subsequent hazard to wildlife can be estimated by using the toxicity data provided by tests on the manufacturing-use chemical.

GUIDE TO USE OF BIBLIOGRAPHY

Guide to Use of This Bibliography

1. Content of Bibliography. This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this standard. The bibliography is divided into 3 sections: (1) citations that contributed information useful to the review of the chemical and considered to be part of the data base supporting registrations under the standard, (2) citations examined and judged to be inappropriate for use in developing the standard, and (3) standard reference material. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. Identification of Entries. The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, an eight-digit numeric identifier. This number is unique to the citations, and should be used at any time specific reference is required. This number is called the "Master Record Identifier", or "MRID". It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. This is also to be used whenever a specific reference is needed.

4. Form of the Entry. In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. The bibliographic conventions used reflect the standards for the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

    a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identificable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

    b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. This is the third element in the citation. In some cases it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parenthesis. For studies submitted to us in the past, the trailing parenthesis include (in addition to any self-explanatory text) the following elements describing the earliest known submission.

    (1) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission.

    (2) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission.

    (3) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

    (4) Volume Identification. The final element in the trailing parenthesis identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th 123456-AA.

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